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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : John H. Lee et al.	Group Art Unit: 1651 Examiner: Francisco Chandler Prats
Appln. No. : 09/392,243	
Filed : September 9, 1999	
Title : Processes For Making Protein Hydrolysates From Animal Peptone And For Preserving Mucosa	
Docket No. : LL11.12-0073	

EXPRESS MAIL COVER SHEET

Assistant Commissioner for Patents
Washington, D.C. 20231

SENT VIA EXPRESS MAIL
Express Mail No.: EV 168042457 US

Sir:

The following papers are being transmitted via **EXPRESS MAIL** to the U.S. Patent and Trademark Office on the date shown below:

1. Brief for Appellant (41Pages) Including 3 sets of the Brief & 3 sets of the following:
 - a. Appendix A (3 pages)
 - b. Appendix B (1 page) Including
 - i. Exhibit A (7 pages)
 - ii. Exhibit B (11 pages)
 - iii. Exhibit C (8 pages)
 - iv. Exhibit D (42 pages)
 - v. Exhibit E (3 pages)
 - c. Appendix C, Including 12 Published Court Cases (76 pages)
2. Fee Transmittal Sheet (1 Page)
3. Check for \$320.00
4. Return receipt Postcard (1 Page)

Respectfully submitted,
KINNEY & LANGE, P.A.

Date: January 6, 2003

By Philip F. Fox

Philip F. Fox, Reg. No. 38,142
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

PFF:alg

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Complete if Known

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Examiner Name	Francisco Chandler Prats
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Total Amount of Payment \$320.00

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1. ☒ The Commissioner is hereby authorized to charge any additional fee required under 37 C.F.R. 1.16 and 1.17 and credit any over payments to Deposit Account No.11-0982. Deposit Account Name: Kinney & Lange, P.A. A duplicate copy of this communication is enclosed

2. ☒ Check Enclosed

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description
1001	750	2001	375	<input type="checkbox"/> Utility Filing Fee
1006	330	2006	165	<input type="checkbox"/> Design Filing Fee
1004	750	2004	375	<input type="checkbox"/> Reissue Filing Fee
1005	160	2005	80	<input type="checkbox"/> Prov. Filing Fee
Subtotal (1) \$				

2. EXTRA CLAIM FEES

	Number Claims	Prior**	Extra	Fee from Below	Fee Paid
Total	*	*	*	*	*
Indep.	*	*	*	*	*
Multiple Dependent Claims			*	*	*

**Insert 3 and 20, or number previously paid if greater; Reissue see below

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple Dependent Claim
1204	84	2204	42	Reissue Independent Claims Over Original Patent
1205	18	2205	9	Reissue claims in excess of 20 and over original patent
Subtotal (2) \$				

FEE CALCULATION (Continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description	Fee paid
1051	130	2051	65	Surcharge - Late filing fee or oath	*
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	*
1053	130	1053	130	Non-English specification	*
1812	2,520	1812	2,520	For Filing a Request for Reexamination	*
1251	110	2251	55	Extension for reply within first month	*
1252	410	2252	205	Extension for reply within second month	*
1253	930	2253	465	Extension for reply within third month	*
1254	1,450	2254	725	Extension for reply within fourth month	*
1255	1,970	2255	985	Extension for reply within fifth month	*
1402	320	2402	160	Filing a brief in support of an appeal	320
1403	280	2403	140	Request for oral hearing	*
1814	110	2814	55	Terminal Disclaimer Fee	*
1452	110	2452	55	Petition to revive - unavoidable	*
1453	1,300	2453	650	Petition to revive - unintentional	*
1501	1,330	2501	680	Utility/Reissue issue fee (inc. advance copies)	*
1502	500	2502	265	Design issue fee (inc. advance copies)	*
1460	130	1460	130	Petitions to the Commissioner	*
1807	50	1807	50	Petitions related to provisional applications	*
1806	180	1806	180	Submission of Information Disclosure Statement	*
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	*
1801	750	2801	375	Request for Continued Examination (RCE)	*
Other fee (specify)					*
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Signature Philip F. Fox
 Philip F. Fox

Date January 6, 2003

Reg. No. 38,142

Deposit Account No. 11-0982



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#20 103
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Inventor : John H. Lee et al.

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Title : Processes For Making Protein Hydrolysates From
Animal Peptone And For Preserving Mucosa

Docket No. : LL11.12-0073

Group Art Unit: 1651

Examiner: Francisco
Chandler Prats

BRIEF FOR APPELLANT

Assistant Commissioner for Patents
Washington, D.C. 20231

SENT VIA EXPRESS MAIL

Express Mail No.: EV 168042457 US

Sir:

This is an appeal from an Office Action dated July 2, 2002, in which claims 21-27 and 36-54 were finally rejected.

REAL PARTY IN INTEREST

The real party in interest is Land O'Lakes Farmland Feed, LLC. of Arden Hills, Minnesota who is the owner of the entire right, title and interest in the application.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences involving the subject matter or issues in this appeal, and there are no known related appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

STATUS OF THE CLAIMS

A. TOTAL NUMBER OF CLAIMS IN THE APPLICATION

Claims in the application are:

Claims 1-54.

B. STATUS OF ALL THE CLAIMS

1. Claims canceled:

Claims 1-20 and 28-35.

2. Claims withdrawn but not canceled:

None.

3. Claims pending:

Claims 21-27 and 36-54.

4. Claims allowed:

None.

5. Claims rejected:

Claims 21-27 and 36-54.

C. CLAIMS ON APPEAL

The claims on appeal are claims 21-27 and 36-54 that are each listed in Appendix A.

STATUS OF AMENDMENTS

An election was made on December 11, 2001 in response to a Restriction/Election requirement; claims 21-27 were elected. An Amendment was filed on April 11, 2002; in this April 11, 2002 Amendment, claims 1-20 and 28-35 were canceled, and claims 36-54 were added. An Amendment After Final was filed on October 2, 2002; in this October 2, 2002 Amendment After Final, claim 42 was amended. In an Advisory Action mailed on October 17, 2002, the Examiner indicated that this amendment to claim 42 would be entered for purposes of Appeal. Applicants have not submitted any further Amendments subsequent to the October 2, 2002 Amendment After Final.

SUMMARY OF INVENTION

Claim 21 is an independent claim that defines a method of preserving mucosa tissue. The method of claim 21 comprising mixing a quantity of mucosa tissue with a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid to yield preserved

mucosa tissue. See page 1, lines 15-17; page 4, lines 1-3; page 5, lines 16-36; page 6, lines 1-3, lines 5-7, and line 20-35; page 9, lines 9-31; page 12, lines 19-22; and page 15, lines 1-3.

Claim 22 depends from independent claim 21. Claim 22 defines the preserving agent as phosphoric acid and further specifies adjusting the pH of the mucosa tissue with phosphoric acid to about 2-4. See page 4, lines 3-6; page 6, lines 22-23; page 12, lines 24-26; page 15, lines 5-7; and page 16, lines 6-7.

Claim 23 depends from independent claim 21. Claim 23 defines the preserving agent as hydrogen peroxide and further specifies mixing less than about 1% by weight of hydrogen peroxide with the mucosa tissue, where the percent by weight of hydrogen peroxide is based upon the weight of the mucosa tissue being taken as 100% by weight. See page 4, lines 15-16; page 5, lines 18-20; page 6, lines 5-7; page 9, lines 15-17; page 12, lines 28-31; and page 15, lines 9-12.

Claim 24 depends from independent claim 21. Claim 24 specifies the preserving agent as hydrogen peroxide, and further specifies heating the mucosa tissue to a temperature in the range of about 50-105°C prior to the mixing step of claim 21. See page 4, lines 11-14; page 5, lines 17 and 35; page 9, lines 13-15; page 12, lines 33-34; and page 15, lines 14-16.

Claim 25 depends from independent claim 21, defines the preserving agent of claim 21 as hydrogen peroxide, and specifies an ash content for the preserved mucosa tissue as less than about 10% by weight, based upon the total weight of the preserved mucosa tissue as 100% by weight. See page 1, lines 17-18; page 4, lines 26-28; page 5, lines 25-27; page 13, lines 12-15; and page 15, lines 18-21.

Claim 26 depends from independent claim 21 and further specifies a standard plate count of less than about 20,000 cfu/g for the preserved mucosa tissue about seven days after the preserving step of claim 21. See page 4, lines 31-32; page 5, lines 27-28; page 13, lines 1-3; page 15, lines 23-25; and page 16, lines 9-11.

Claim 27 depends from independent claim 21 and further specifies an *E. Coli* count of less than about 10 cfu/g for the preserved mucosa tissue about seven days after the preserving step. See page 4, line 36, through page 5, line 2; page 5, lines 27-28; page 13, lines 5-6; page 15, lines 27-28; and page 16, lines 13-15.

Claim 36 is an independent claim that defines a method of treating mucosa tissue. According to claim 36, the method comprises combining the mucosa tissue and a peroxide-containing compound to form an intermediate. See page 1, lines 15-17; page 4, 1-3; page 5, lines 16-36; page 6, lines 1-3 and lines 5-7; page 9, lines 9-31; page 12, lines 28-34; page 13, lines 12-15; and page 15, lines 1-3 and lines 30-32.

Claim 37 depends from independent claim 36 and defines the peroxide-containing compound as hydrogen peroxide. See page 1, lines 15-17; page 4, 1-3; page 5, lines 16-36; page 6, lines 1-3 and lines 5-7; page 9, lines 9-31; page 12, lines 28-34; page 13, lines 12-15; and page 15, lines 1-3 and lines 30-32.

Claim 38 depends from independent claim 36. Claim 38 specifies that the concentration of the peroxide-containing compound in the intermediate of claim 36 is initially less than about 1% by weight, based upon the total weight of the mucosa tissue and the peroxide-containing compound being 100% by weight. See page 5, lines 18-20; page 6, lines 5-7; and page 9, lines 15-17.

Claim 39 depends from dependent claim 38 and specifies less than about 0.5% by weight for the initial concentration of the peroxide-containing compound in the intermediate of claim 38, based upon the total weight of the mucosa tissue and the peroxide-compound being 100% by weight. See page 6, lines 5-7.

Claim 40 depends from independent claim 36. Claim 40 further specifies mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, where the concentration of the peroxide-containing compound remaining in the mucosa product is less than about 0.04% by weight, based upon the total weight of the mucosa product being 100% by weight. See page 4, lines 19-23; page 5, lines 19-25; page 9, lines 23-25; and page 16, lines 1-4.

Claim 41 depends from independent claim 36. Claim 41 further specifies mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, where the concentration of the peroxide-containing compound remaining in the mucosa product is less than about 0.01% by weight, based upon the total weight of the mucosa product being 100% by weight. See page 4, lines 19-23; page 5, lines 19-25; and page 9, lines 23-25.

Claim 42 depends from independent claim 36. Claim 42 further specifies mixing the peroxide-containing compound and the mucosa tissue of claim 36 to form a mucosa product, where the concentration of the peroxide-containing compound remaining in the mucosa product is undetectable when the concentration of the peroxide-containing compound remaining in the mucosa product is determined using KMnO_4 titration. See page 4, lines 19-23; page 5, lines 19-25; and page 9, lines 23-25.

Claim 43 depends from independent claim 36. Claim 43 further heating the mucosa tissue of claim 36 to a temperature in the range so of about 50-105°C prior to combining the peroxide-containing compound and the mucosa tissue. See page 4, lines 11-14; page 5, lines 17 and 35; page 9, lines 13-15; page 12, lines 33-34; and page 15, lines 14-16.

Claim 44 depends from independent claim 36. Claim 44 further specifies heating the mucosa tissue of claim 36 to a temperature in the range of about 65-75°C prior to combining the peroxide-containing compound and the mucosa tissue. See page 4, lines 11-14; page 5, line 17; and page 9, lines 13-15.

Claim 45 depends from independent claim 36 and further specifies that the mucosa tissue of claim 36 comprising substantially non-hydrolyzed mucosa tissue. See page 4, lines 1-3; page 5, lines 17-18; and page 13, lines 17-20.

Claim 46 depends from dependent claim 45. Claim 46 further specifies the intermediate of claim 36 as a treated mucosa product and further specifies hydrolyzing the treated mucosa product to form a hydrolyzed mucosa product. See page 1, lines 11-13; page 5, line 32, through page 6, line 3; and page 9, lines 18-23.

Claim 47 depends from dependent claim 46 and further defines the hydrolyzed mucosa product as comprising heparin. Claim 47 further species extracting heparin from the hydrolyzed mucosa product. See page 1, lines 11-13; and page 6, lines 7-10.

Claim 48 depends from dependent claim 46 and further specifies contacting the hydrolyzed mucosa product with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reduce enzymatic

activity of the hydrolyzed mucosa product. See page 1, lines 8-9 and lines 13-15; page 2, lines 26-32; and page 3, lines 3-35.

Claim 49 depends from independent claim 36 and further specifies that the mucosa tissue of claim 36 comprises hydrolyzed mucosa tissue. See page 5, line 32, through page 6, line 3; page 6, lines 5-7; and page 9, lines 27-28.

Claim 50 depends from dependent claim 49 and further defines contacting the hydrolyzed mucosa tissue with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reduce enzymatic activity of the hydrolyzed mucosa tissue. See page 9, lines 27-28.

Claim 51 depends from independent claim 36 and further defines the intermediate of claim 51 as being a treated mucosa product with an ash concentration of less than about 10% by weight, based upon the total weight of the treated mucosa product being 100% by weight. See page 1, lines 17-18; page 4, lines 26-28; page 5, lines 25-27; page 13, lines 12-15; and page 15, lines 18-21.

Claim 52 depends from dependent claim 51 and further defines an ash content of less than about 7% by weight for the treated mucosa product, based upon the total weight of the treated mucosa product being 100% by weight. See page 4, line 26-28.

Independent claim 53 defines a method of treating mucosa tissue that comprises adding phosphoric acid to the mucosa tissue to form an intermediate. See page 1, lines 15-17; page 4, lines 1-3; page 6, lines 20-35; and page 12, lines 19-26.

Claim 54 depends from independent claim 53. Claim 54 further specifies the intermediate of claim 53 as initially having a pH in the range of about 2-4 after the phosphoric acid is added to the mucosa tissue. See page 4, lines 3-6; page 6, lines 22-23; page 12, lines 24-26; page 15, lines 5-7; and page 16, lines 6-7.

DESCRIPTION OF REFERENCES RELIED ON BY THE EXAMINER

Copies of the references discussed below are provided in Appendix B to this Brief For Appellant.

U.S. Patent No. 5,607,840 to Van Gorp et al. (subsequently referred to as the "Van Gorp patent") (attached as Exhibit A) discloses a method of producing protein hydrolysate from animal tissue that has an endothelial or mucosal component (mucosa). (Col. 4, lines 9-11). The Van Gorp patent discloses treatment of the mucosa with either chemical means or physical means to stabilize the mucosa. (Col. 4, lines 17-19 and lines 46-50). Physical means of stabilizing the mucosa include heating the mucosa tissue to a temperature ranging between 50°C and 95°C. Chemical means of stabilizing the mucosa principally include treatment of the mucosa with an oxygen scavenger, such as sodium metabisulfite, though treatment with an antioxidant, such as BHA or BHT, or, in environments with low acidity, calcium propionate is also mentioned. (Col. 4, lines 22-35). An extraction process that is based upon use of an added extraction salt is performed upon the stabilized mucosa tissue, and the extracted constituents and extracting salts are separated from the remaining mucosa tissue. (Col. 4, lines 51-59). The post-extraction mucosa tissue is then heated to 55°C, and the pH is adjusted with an appropriate agent, such as liquid caustic soda, to a pH appropriate for activity of a selected enzyme. (Col. 4, lines 60-63). Approximately 1.5 grams of enzyme per kilo of post-extraction mucosa tissue is added to hydrolyze the post-extraction mucosa tissue, preferably under constant agitation for between 4 and 24 hours, while maintaining a temperature at 45°C-65°C. (Col. 4, line 65 - Col. 5, line 3). The enzymatic action is interrupted by raising the temperature to 90°C for about 30 minutes, and the hydrolyzed product is then recovered. (Col. 5, lines 3-9).

U.S. Patent No. 4,438,100 to Balslev et al. (subsequently referred to as the "Balslev patent") (attached as Exhibit B) discloses sterilized, preserved, stable mucine-containing compositions and methods for their preparation. (Col. 1, lines 5-7). The solutions are adapted for oral or nasal application in human beings as well as for ophthalmic solutions. (Col. 1, lines 32-35). Low bacteria counts in the solutions are obtained by sterilization and by use of a preservative that is incorporated in the solution. (Col. 4, lines 45-50). Preservatives that have antimicrobial properties

include oxidizing bactericides including peroxides, such as hydrogen peroxide. (Col 4, lines 56-60). The oxidizing bactericides, such as hydrogen peroxide, serves as a microbiocidal agent and also helps eliminate mucine-decomposing enzymatic activity. (Col. 6, lines 8-12).

U.S. Patent No. 4,145,451 to Oles (subsequently referred to as the "Oles patent") (attached as Exhibit C) discloses food compositions that are preserved by a combination of (1) acetic acid or other organic acid and (2) phosphoric acid that, collectively, have been found to have a synergistic effect. (Col 2, lines 27-34). Foods disclosed as benefitting from the synergistic preservative effect of the combination of (1) acetic acid or other organic acid and (2) phosphoric acid include oil or oilless, pourable or viscous, emulsified or nonemulsified food products commonly used as an adjunct on salads, vegetables, sandwiches and the like, including mayonnaise, salad dressing, and French dressing. (Col. 2, lines 40-48).

ISSUES

- I. Whether claims 21-27 are obvious under 35 U.S.C. § 103(a) as being unpatentable over the Van Gorp patent in view of the Balslev patent and the Oles patent.
- II. Whether claims 36-52 are obvious under 35 U.S.C. § 103(a) as being unpatentable over the Van Gorp patent in view of the Balslev patent.
- III. Whether claims 53 and 54 are obvious under 35 U.S.C. § 103(a) as being unpatentable over the Van Gorp patent in view of the Oles patent.
- IV. Whether claim 42 is indefinite under 35 U.S.C. §112, second paragraph.

GROUPING OF CLAIMS

The following groupings of claims are made solely in the interest of consolidating issues and expediting this Appeal. No grouping of claims is intended to be, nor should be interpreted

as being, any form of admission or a statement as to the scope or obviousness of any feature of any claim.

Claims 21-27 and 36-54 do not stand or fall together. Instead, claims 21-27 and 36-54 are divided into the following seven groups. The claims of each individual group are to be separately considered in relation to particular rejections:

Group No. 1: claims 21, 26, and 27.

Group No. 2: claim 24.

Group No. 3: claims 23, 25, 36-41, 45-47, 49, and 51-52.

Group No. 4: claim 42

Group No. 5: claims 43 and 44.

Group No. 6: claims 48 and 50.

Group No. 7: claims 22, 53, and 54.

ARGUMENT

I. Standard For Determining a Prima Facie Case of Obviousness.

Under 35 U.S.C. §103(a), the Examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To establish a prima facie case of obviousness, the Examiner must show some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *Id.* A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983). If the Examiner does not establish a prima facie case of obviousness, the rejection is improper and will be overturned. *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993).

II. The Van Gorp Patent, In View of The Balslev Patent And The Oles Patent, Does Not Teach, Suggest Or Make Obvious The Invention Of The Present Application, As Defined In Claims 21-27.

A. The Examiner Impermissibly Relied On Hindsight Reconstruction When Alleging Claim 21 Is Obvious.

The Examiner clearly used the features defined in claim 21 as a map to find and combine details when alleging the present invention, as defined in claim 21, is obvious. It is improper to use hindsight reconstruction to pick and choose among isolated disclosures in the prior art. *In re Fine*, 5 U.S.P.Q.2d at 1600. An Examiner should forget the invention at issue when considering whether it would be obvious to modify a prior art disclosure. *W. L. Gore*, 220 U.S.P.Q. at 312-13. The Examiner improperly relied on hindsight reconstruction when combining details from the Balslev patent and details from the Oles patent with details from the Van Gorp patent to arrive at the invention defined in claim 21.

Admittedly, the Van Gorp patent is relevant prior art because the Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. However, the method disclosed in the Van Gorp patent, standing alone, does not fully disclose the present invention, as defined in claim 21. Consequently, the Examiner chose to erroneously rely on the combination of details from the Van Gorp patent with details from the Balslev patent and details from the Oles patent in an attempt to allege claim 21 is obvious and therefore allegedly unpatentable.

There is no connection between the Van Gorp patent, the Balslev patent, and the Oles patent except for the invention defined in claim 21. The Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. On the other hand, the Balslev patent discloses a pharmaceutical type product that is used as an artificial saliva, ophthalmic solutions and carriers for medicaments. (See last sentence of abstract). Still further, the Oles patent discloses food products that are preserved without use of artificial preservatives by the synergistic effect of (1) acetic acid or other organic acids in combination with (2) phosphoric acid. (Col. 2, lines 31-34). The Examiner's combination of details from these references must fail to avoid improper hindsight reconstruction.

One skilled in the art would not attempt to combine process details concerning the industrial preservation of pig guts, where proteins of the pig guts are later broken down with an enzyme by hydrolysis, with details about formation of a pharmaceutical product such as artificial saliva and with details about formation of a food stuff, such as mayonnaise and salad dressing. Instead, the Examiner picked and chose elements from entirely unrelated references in an attempt to remedy the deficiencies of the Van Gorp patent and find claim 21 obvious. The Examiner improperly used the features defined in claim 21 as a map to find and combine details when alleging the present invention, as defined in claim 21, is obvious. Therefore, the Examiner's rejection of claim 21 as allegedly being obvious should be reversed.

B. There Is No Teaching Or Suggestion In The Prior Art Which Would Lead One Skilled In The Art To Combine The Cited References.

The Examiner alleged claim 21 was unpatentable over the Van Gorp patent in view of the Balslev patent and the Oles patent. Nonetheless, despite the Examiner's rejection, the Van Gorp, Balslev, and Oles patents, either separately or in any combination, do not teach, suggest, disclose, or make obvious the invention of the above-identified application, as defined in claims 21-27. Claim 21 reads as follows:

A method for preserving mucosa tissue comprising mixing a quantity of mucosa tissue with a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid to yield the preserved mucosa tissue.

The Examiner rejected claim 21 in an Office Action mailed on January 11, 2002 where the Examiner alleged the following:

Van Gorp discloses a process wherein a mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. *See* col.4, lines 17-34 and 45-50. Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claim 24. Note further that because it contains the same material, mucosa, Van Gorp's preserved product would inherently have the same ash amount as recited in the claims.

Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. However, each of Oles (see, e.g., abstract) and Balslev (see e.g., abstract) make it clear that both phosphoric acid and peroxide were well known preservatives in food and/or pharmaceutical applications. Thus, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev would have functioned equivalently to the preservatives disclosed by Van Gorp, the artisan of ordinary skill would have been motivated to have substituted Oles' phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.

The Examiner improperly combined details from the Oles patent with details from the Van Gorp patent when alleging the invention defined in claim 21 is obvious and also improperly combined details from the Balslev patent with details from the Van Gorp patent when alleging the invention defined in claim 21 is obvious.

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the **relevant** art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972)(emphasis added). In rejecting claim 21 as allegedly being obvious, the Examiner attempted to combine details from a patent disclosing preservation of pig tissues prior to hydrolysis of proteins from the pig tissues *with* details from patents the Examiner admitted were part of the food and pharmaceutical arts. The food and pharmaceutical arts are not relevant to the preservation of proteins prior to hydrolysis. Therefore, for this initial reason, the Examiner's combination of references is improper.

The Examiner's simplistic attempt to justify the combination of details from the Van Gorp patent with details from the Balslev patent and with details from the Oles patent hinges on the Examiner's so-called "well known preservative" theory. In essence, the Examiner's argues the Van Gorp patent discloses use of "well known preservatives" to preserve mucosa tissue. Similarly, according to the Examiner, the Balslev patent and the Oles patent allegedly also disclose "well

known preservatives.” Therefore, since only “well known preservatives” are employed in the three references, and all “well known preservatives” are allegedly equivalent and substitutable for each other (apparently, no matter the application, per the Examiner), all “well known preservatives” can be substituted for each other between the three references.

As convenient as the “well known preservative” theory is, it does not conform to established law. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992).

There is no teaching or suggestion in the Van Gorp patent disclosure to use any preservative other than an oxygen scavenger, an antioxidant, or, in low acidity environments, calcium propionate. (Col. 4, lines 22-35). In this regard, the Van Gorp patent principally mentions use of sodium metabisulfite as an oxygen scavenger, while also referencing use of calcium propionate, BHT, and BHA as alternatively acceptable preservatives. (Col. 4, lines 25-34).

The Examiner attempted to make the combination of references with an unsubstantiated, speculative statement that: “the claimed substitution of well known preservatives for those used in Van Gorp must be an obvious substitution of one known equivalent for another.” The Examiner must provide reasons why the Examiner’s combination of references is permitted. The Examiner failed to provide any reason except for the speculative, simplistic, and self-serving “well known preservative” theory.

While the Examiner provided no factual bases for the improper combination of references, Applicants submitted evidence to the Examiner showing that most chemical agents have only very specific food preservation actions and functionalities and therefore must be carefully matched to the particular preservation action desired. Jay, James M., Modern Food Microbiology, pages 259-296 (Van Nostrand Reinhold 1986) (attached as Exhibit D). Indeed, some chemical agents are active only against molds while other chemical agents are active only against yeast and still other agents are active only against certain bacteria. *Id.* Furthermore, most chemical agents

require specific conditions of pH, moisture, and/or temperature to function effectively as preservatives. *Id.*

The details provided throughout the Exhibit D reference demonstrate there is no support whatsoever for the Examiner's allegation that the Oles phosphoric acid "would have functioned equivalently to the preservatives disclosed by Van Gorp" and therefore "must be considered an obvious substitution of one known equivalent preservative for another." Indeed, the mere fact that the Oles patent relies on a synergistic combination of acidifying agents (a combination of (1) acetic acid or other organic acid and (2) phosphoric acid), whereas the Van Gorp patent principally relies on an oxygen-scavenging stabilizer (while also mentioning anti-oxidants and, for low acidity environments, calcium propionate) demonstrates the wide difference in operating function between the preservatives of the Van Gorp patent and the preservatives of the Oles patent. There simply is no reasonable basis for believing an "artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles . . . that phosphoric acid . . . would have functioned equivalently to the preservatives disclosed by Van Gorp" and would therefore "have been motivated to have substituted Oles' phosphoric acid . . . for the preservatives disclosed by Van Gorp," despite the Examiner's conclusory allegation to the contrary.

Furthermore, the Examiner's reasoning is contrary to the holding in *In re Mills*. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). The Van Gorp patent suggests the use of oxygen scavengers as preservatives. The Van Gorp patent does not suggest incorporation of either an oxidizer (such as hydrogen peroxide) or an acidifier (such as phosphoric acid) in the process disclosed in the Van Gorp patent. The Examiner has not provided any proof that either hydrogen peroxide or phosphoric acid serve as oxygen scavengers or are otherwise equivalent in function to any of the preservatives disclosed in the Van Gorp patent. There is no teaching in the Van Gorp patent that suggests the desirability of incorporating the preservatives disclosed in either the Balslev patent or in the Oles patent into the process of the Van Gorp patent.

The Examiner improperly combined details from the Oles patent with details from the Van Gorp patent when alleging the invention defined in claim 21 is obvious and also improperly combined details from the Balslev patent with details from the Van Gorp patent when alleging the invention defined in claim 21 is obvious. The mere fact that the preservatives disclosed in the Balslev patent and/or the Oles patent **may** be used in the Van Gorp patent does not necessarily render claim 21 unpatentable as allegedly being obvious. The Examiner has not met his burden of showing a teaching or suggestion to combine details from the three different references; therefore the Examiner's obviousness rejection should be reversed.

Furthermore, the Examiner mischaracterizes the preservative disclosed in the Oles patent. The Oles patent clearly and plainly discloses a synergistic effect between two different components: (1) phosphoric acid and (2) acetic acid or another organic food acid. "The food compositions of the present invention contain a synergistic combination of acetic acid or other organic food acid and phosphoric acid." (Col. 2, lines 31-34). The Oles patent teaches preserving foods with an organic acid and phosphoric acid, not phosphoric acid alone. Claim 21 defines the invention as having "a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid." The invention that claim 21 defines is not defined as a preserving agent that includes phosphoric acid and another ingredient working in synergy.

The Examiner attempted to address this point by arguing claim 21 is open-ended because of the comprising language. While the Examiner is correct that the claim 21 language is open-ended because of the comprising language of the preamble, a Markush grouping (i.e. "a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid") is not open-ended. "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *In re Driscoll*, 562 F.2d 1245, 195 USPQ 434 (CCPA 1977). In a Markush grouping it is improper to use the term "comprising" instead of "consisting of." *Ex parte Dotter*, 12 U.S.P.Q. 382 (Bd. App. 1931).

Claim 21 uses “consisting of” language that limits the scope of the Markush group to those chemicals or ingredients listed. The Markush group of claim 21 is not open-ended as suggested by the Examiner. The Markush group employed in claim 21 lists only hydrogen peroxide or phosphoric acid as preserving agents, and does not include a preserving agent that includes a combination of phosphoric acid and an organic food acid, as disclosed in the Oles patent.

The Oles patent does not disclose phosphoric acid by itself as a preserving agent. Rather the Oles patent discloses use of (1) phosphoric acid with (2) an organic acid as a preserving agent. This combination of preservative ingredients falls outside the scope of claim 21. Therefore, the Examiner’s combination of details from the Van Gorp patent and from the Oles patent does not render claim 21 obvious.

Furthermore, the Balslev patent actually teaches away from using hydrogen peroxide as a preservative in the process disclosed in the Van Gorp patent. The Van Gorp patent principally teaches preservation by scavenging oxygen from the mucosa tissue with oxygen scavengers. (Col. 4, lines 23-25). According to the Balslev patent, the hydrogen peroxide serves as an oxidizing bactericide. (Col. 6, lines 5-10). By definition, to oxidize means (1) to combine with oxygen; (2) to dehydrogenate especially by the action of oxygen; or (3) to change (a compound) by increasing the proportion of the electronegative part or change (an element or ion) from a lower to a higher position valence: remove one or more electrons from (an atom, ion, or molecule). Merriam-Webster Dictionary, www.m-w.com. (Attached as Exhibit E). An oxidizing agent provides oxygen to an active site via a chemical reaction. Providing oxygen to mucosa tissue is exactly the opposite result of that desired by the preservatives principally employed in the Van Gorp patent, namely, scavenging oxygen.

In addition to providing oxygen to the mucosa tissue, hydrogen peroxide also is said to serve in the Balslev patent as “a means to eliminate mucine-decomposing enzymatic activity.” (Col. 6, lines 10-12). The Balslev patent actively employs hydrogen peroxide in the Balslev process for the stated purpose of destroying enzymatic activity. (Col. 11, lines 35-41).

A chemical that destroys enzymatic activity would not be a useful preservative in a process whose desired effect is the hydrolysis of proteins by enzymatic activity, as disclosed in the

process of the Van Gorp patent. The use of hydrogen peroxide would hinder or defeat the desired result (hydrolysis of proteins with enzymes) of the process disclosed in the Van Gorp patent. Therefore, use of hydrogen peroxide as disclosed in the Balslev patent teaches away from incorporation of hydrogen peroxide in the process disclosed in the Van Gorp patent. As such, the Examiner's combination of the Van Gorp patent and the Balslev patent is improper and the rejection must be reversed.

For the above stated reasons, incorporation of the preservatives disclosed in the Balslev patent or incorporation of the preservatives disclosed in the Oles patent into the process disclosed in the Van Gorp patent is improper. There is no teaching or suggestion in the cited references that would lead one skilled in the art to combine the references. In fact, the references actually teach away from the Examiner's suggested combination. The obviousness rejection of claim 21 based upon the Van Gorp patent in view of the Balslev patent and the Oles patent is improper and should be reversed..

C. Claim 24 Defines A Heating Step That Is Not Disclosed In The Prior Art.

The Van Gorp patent does not disclose the method of heating the preserved mucosa tissue as defined in claim 24. Claim 24 depends from independent claim 21 and reads as follows:

The method of claim 21, wherein said preserving agent is hydrogen peroxide, and further including the step of heating said mucosa tissue to a temperature of from about 50-105°C prior to said mixing step.

Claim 24 thus requires heating the mucosa tissue prior to combination of the hydrogen peroxide or peroxide-containing compound with the mucosa tissue and thus each require a combination of heating and preservative addition.

The Examiner relies only on the Van Gorp patent for the disclosure that allegedly includes both preservative addition and heating:

Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claims 24, 43 and 44.

(Page 3, second complete paragraph, of the Office Action mailed on July 2, 2002). However, the heating referred to by the Examiner is a *physical* treatment that is specified in the Van Gorp patent as an alternative to the described chemical treatment:

When the raw material is transported or stored for a period of time before processing, it is preferably treated by physical or chemical means to inhibit bacterial growth. Physical means include temperature elevation into the range between 50 degrees C. and 95 degrees C. Chemical means include the use of a bacteriostat or bacteriocide.

(Column 4, lines 17-22, of the Van Gorp patent). (Emphasis added). Clearly, the Van Gorp patent calls for heating or preservative addition and does not teach, suggest, or disclose that the heating and preservative addition both occur in combination. On the other hand, claim 24 requires *both* heating and preservation agent addition. Furthermore, neither the remainder of the Van Gorp patent, nor the Balslev patent, nor the Oles patent includes any teaching, suggestion, or disclosure that both heating and preservative addition be employed or that the substrate be heated to the temperatures in the range specified by claim 24 prior to adding a chemical preservative. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). Here, none of the three references the Examiner relies upon teaches, suggests, or motivates the combination of *both* heating and preservation agent addition that claim 24 requires.

Claims 24 is in allowable form. Therefore, Applicants respectfully request that the Board reverse the obviousness rejection of claim 24 under 35 U.S.C. §103 based upon the Van Gorp, Balslev, and Oles patents and that claim 24 be allowed.

D. Claims 22-27 Are Allowable Because Claims 22-27 Each Depend From Allowable Independent Claim 21.

Claims 22-27 were rejected as allegedly being obvious considering details from the Van Gorp patent in view of details from the Balslev patent and the Oles patent. Claims 22-27 are

each dependent upon independent claim 21. Claim 21 is allowable and non-obvious. see §§ II. A and B. Because claim 21 is allowable and non-obvious, claims 22-27, which depend from claim 21, are also allowable and non-obvious. Applicants respectfully request that the Board reverse the obviousness rejection of claims 22-27 under 35 U.S.C. §103 based upon the Van Gorp, Balslev, and Oles patents and that claims 22-27 be allowed.

III. The Van Gorp Patent In View Of The Balslev Patent Does Not Teach, Suggest Or Make Obvious The Invention of The Present Application As Defined In Claims 36-52.

A. The Examiner Impermissibly Relied On Hindsight Reconstruction When Alleging Claim 36 Is Obvious.

The Examiner clearly used the features defined in claim 36 as a map to find and combine details when alleging the present invention, as defined in claim 36, is obvious. It is improper to use hindsight reconstruction to pick and choose among isolated disclosures in the prior art. *In re Fine*, 5 U.S.P.Q.2d at 1600. An Examiner should forget the invention at issue when considering whether it would be obvious to modify a prior art disclosure. *W. L. Gore*, 220 U.S.P.Q. at 312-13. The Examiner improperly relied on hindsight reconstruction when combining details from the Oles patent with details from the Van Gorp patent to arrive at the invention defined in claim 36.

The Oles patent was cited for the alleged proposition that phosphoric acid is a well known preservative. Since neither independent claim 36 nor dependent claims 37-52 include phosphoric acid as an element, the Oles patent is not relevant to the non-obviousness analysis of claims 36-52. As such, the Oles patent will not be discussed in §III of this Brief.

Admittedly, the Van Gorp patent is relevant prior art because the Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. However, the method disclosed in the Van Gorp patent, standing alone, does not fully disclose the present invention, as defined in claim 36 does not disclose combining the mucosa tissue with a peroxide-containing compound. The Balslev patent does disclose use of hydrogen peroxide as a preservative in the pharmaceutical art. However, the art of preserving mucosa tissue and the pharmaceutical art

are unrelated and there is no teaching in either patent that would lead to the Examiner's combination of references. Nonetheless, the Examiner relies, albeit erroneously, on the combination of details from the Van Gorp patent with details from the Balslev patent in an attempt to allege claim 36 is obvious and therefore allegedly unpatentable.

There is no connection between the Van Gorp patent and the Balslev patent except for the invention defined in claim 36. The Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. On the other hand, the Balslev patent discloses a pharmaceutical type product that is used as an artificial saliva, ophthalmic solutions and carriers for medicaments. (See last sentence of abstract). The Examiner's combination of details from these references must fail to avoid improper hindsight reconstruction.

One skilled in the art would not attempt to combine process details concerning the industrial preservation of pig guts, where proteins of the pig guts are later broken down with an enzyme by hydrolysis, with details about formation of a pharmaceutical product such as artificial saliva. Instead, the Examiner picked and chose elements from entirely unrelated references in an attempt to remedy the deficiencies of the Van Gorp patent and find claim 36 obvious. The Examiner improperly used the features defined in claim 36 as a map to find and combine details when alleging the present invention, as defined in claim 36, is obvious. Therefore, the Examiner's rejection of claim 36 as allegedly being obvious should be reversed. The arguments presented above in this § III. A are equally applicable to claims 23 and 25 that each specify a peroxide-containing compound, namely hydrogen peroxide. Therefore, the Examiner's rejection of claims 23 and 25 as allegedly being obvious is also improper and should be reversed.

B. There Is No Teaching Or Suggestion In The Prior Art Which Would Lead One Skilled In The Art To Combine The Cited References.

The Examiner alleged claim 36 was unpatentable over the Van Gorp patent in view of the Balslev patent. Nonetheless, despite the Examiner's rejection, the Van Gorp patent in view of the Balslev patent, either separately or in any combination, do not teach, suggest, disclose, or

make obvious the invention of the above-identified application, as defined in claims 36-52. Claim 36 reads as follows:

A method of treating mucosa tissue, the method comprising combining the mucosa tissue and a peroxide-containing compound to form an intermediate.

The Examiner rejected claim 36 in an Office Action mailed on July 2, 2002. The Examiner alleged the following:

Van Gorp discloses a process wherein a mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. *See* col.4, lines 17-34 and 45-50. Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claim 24. Note further that because it contains the same material, mucosa, Van Gorp's preserved product would inherently have the same ash amount as recited in the claims.

Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. However, each of Oles (see, e.g., abstract) and Balslev (see e.g., abstract) make it clear that both phosphoric acid and peroxide were well known preservatives in food and/or pharmaceutical applications. Thus, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev would have functioned equivalently to the preservatives disclosed by Van Gorp, the artisan of ordinary skill would have been motivated to have substituted Oles' phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.

The Examiner improperly combined details from the Balslev patent with details from the Van Gorp patent when alleging the invention defined in claim 36 is obvious.

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the **relevant** art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173

U.S.P.Q. 560, 562 (C.C.P.A. 1972)(emphasis added). In rejecting claim 36 as allegedly being obvious, the Examiner attempted to combine details from a patent disclosing preservation of pig tissues prior to hydrolysis of proteins from the pig tissues *with* details from patents the Examiner admitted were part of the pharmaceutical art. The pharmaceutical art is not relevant to the preservation of proteins prior to hydrolysis. Therefore, for this initial reason, the Examiner's combination of references is improper

The Examiner's simplistic attempt to justify the combination of details from the Van Gorp patent with details from the Balslev patent hinges on the Examiner's so-called "well known preservative" theory. In essence, the Examiner's argues the Van Gorp patent discloses use of "well known preservatives" to preserve mucosa tissue. Similarly, according to the Examiner, the Balslev patent allegedly also discloses "well known preservatives." Therefore, since only "well known preservatives" are employed in the three references, and all "well known preservatives" are allegedly equivalent and substitutable for each other (apparently, no matter the application, per the Examiner), all "well known preservatives" can be substituted for each other between the three references.

As convenient as the "well known preservative" theory is, it does not conform to established law. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992).

There is no teaching or suggestion in the Van Gorp patent disclosure to use any other preservative other than an oxygen scavenger, an antioxidant, or, in low acidity environments, calcium propionate. (Col. 4, lines 22-35). In this regard, the Van Gorp patent principally mentions use of sodium metabisulfite as an oxygen scavenger, while also referencing use of calcium propionate, BHT, and BHA as alternatively acceptable preservatives. (Col. 4, lines 25-34).

The Examiner attempted to make the combination of references with an unsubstantiated, speculative statement that: "the claimed substitution of well known preservatives for those used in Van Gorp must be an obvious substitution of one known equivalent for another."

The Examiner must provide reasons why the Examiner's combination of references is permitted. The Examiner failed to provide any reason except for the speculative, simplistic, and self-serving "well known preservative" theory.

While the Examiner provided no factual bases for the improper combination of references, Applicant submitted evidence to the Examiner showing that most chemical agents have only very specific food preservation actions and functionalities and therefore must be carefully matched to the particular preservation action desired. Jay, James M., Modern Food Microbiology, pages 259-296 (Van Nostrand Reinhold 1986) (attached as Exhibit D). Indeed, some chemical agents are active only against molds while other chemical agents are active only against yeast and still other agents are active only against certain bacteria. *Id.* Furthermore, most chemical agents require specific conditions of pH, moisture, and/or temperature to function effectively as preservatives. *Id.*

Furthermore, the Examiner's reasoning is contrary to the holding in *In re Mills*. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). The Van Gorp patent principally suggests use of oxygen scavengers as preservatives. The Van Gorp patent does not suggest incorporation of an oxidizer (such as hydrogen peroxide) in the process disclosed in the Van Gorp patent. The Examiner has not provided any proof that hydrogen peroxide serves as an oxygen scavenger or is otherwise equivalent in function to any of the preservatives disclosed in the Van Gorp patent. There is no teaching in the Van Gorp patent that suggests the desirability of incorporating the preservatives disclosed in the Balslev patent into the process of the Van Gorp patent.

The Examiner improperly combined details from the Balslev patent with details from the Van Gorp patent when alleging the invention defined in claim 36 is obvious. The mere fact that the preservatives disclosed in the Balslev patent **may** be used in the Van Gorp patent does not necessarily render claim 36 unpatentable as allegedly being obvious. The Examiner has not met his burden of showing a teaching or suggestion to combine details from the two different references; therefore the Examiner's obviousness rejection should be reversed.

Furthermore, the Balslev patent actually teaches away from using hydrogen peroxide as a preservative in the process disclosed in the Van Gorp patent. The principal preserving agent in the Van Gorp patent teaches preservation by scavenging oxygen from the mucosa tissue with oxygen scavengers. (Col. 4, lines 23-25). According to the Balslev patent, the hydrogen peroxide serves as an oxidizing bactericide. (Col. 6, lines 5-10). By definition, to oxidize means (1) to combine with oxygen; (2) to dehydrogenate especially by the action of oxygen; or (3) to change (a compound) by increasing the proportion of the electronegative part or change (an element or ion) from a lower to a higher position valence: remove one or more electrons from (an atom, ion, or molecule). Merriam-Webster Dictionary, www.m-w.com. (Attached as Exhibit E). An oxidizing agent provides oxygen to an active site via a chemical reaction. Providing oxygen to mucosa tissue is exactly the opposite result of that desired by the preservatives principally employed in the Van Gorp patent, namely, scavenging oxygen.

In addition to providing oxygen to the mucosa tissue, hydrogen peroxide also is said to serve in the Balslev patent as “a means to eliminate mucine-decomposing enzymatic activity.” (Col. 6, lines 10-12). The Balslev patent actively employs hydrogen peroxide in the Balslev process for the stated purpose of destroying enzymatic activity. (Col. 11, lines 35-41).

A chemical that destroys enzymatic activity would not be a useful preservative in a process whose desired effect is the hydrolysis of proteins by enzymatic activity, as disclosed in the process of the Van Gorp patent. The use of hydrogen peroxide would hinder or defeat the desired result (hydrolysis of proteins with enzymes) of the process disclosed in the Van Gorp patent. Therefore, use of hydrogen peroxide as disclosed in the Balslev patent teaches away from incorporation of hydrogen peroxide in the process disclosed in the Van Gorp patent. As such, the Examiner’s combination of the Van Gorp patent and the Balslev patent is improper and the rejection must be reversed.

Lastly, the Examiner attempted to justify the Examiner’s combination of details from the Van Gorp patent with details from the Balslev patent in an Advisory Action mailed on October 17, 2002. In the Advisory Action, the Examiner alleged the following:

Lastly, regarding the alleged teaching away from the combination of Van Gorp’s enzymes and Balslev peroxide based on the supposed

inactivation of the enzymes by the peroxide, note again that the preservative in Van Gorp is to be added to the mucosa prior to storage, and that Balslev clearly discloses that the peroxide content ultimately reduces to nothing. Thus, there is no clear teaching away. Moreover, applicant has not demonstrated through direct evidence that the peroxide concentrations of Balslev would have in fact inhibited Van Gorp's proteolytic enzymes. Thus, to the extent it is not based on facts in the record, it is applicant's argument which is technically speculative in this regard.

(Advisory Action dated October 17, 2002, p. 5). The Examiner missed the point of Applicants' argument that prompted this Advisory Action contention of the Examiner. The Examiner, not the Applicant, has the initial burden of providing information substantiating that the alleged combination of references is proper. The Examiner has provided no information explaining why the Examiner's combination is allegedly proper except for the Examiner's "well known preservative" theory. The Examiner has wholly ignored the teachings of the references and has not met the Examiner's burden of proof.

For the above stated reasons, incorporation of the preservatives disclosed in the Balslev patent into the process disclosed in the Van Gorp patent is improper. There is no teaching or suggestion in the cited references that would lead one skilled in the art to combine the references. In fact, the references actually teach away from the Examiner's suggested combination. The obviousness rejection of claim 36 based upon the Van Gorp patent in view of the Balslev patent is improper and should be reversed. The arguments presented above in this § III. B are equally applicable to claims 23 and 25 that each specify a peroxide-containing compound, namely hydrogen peroxide. Therefore, the obviousness rejection of claims 23 and 25 based upon the Van Gorp patent in view of the Balslev patent is also improper and should be reversed.

C. Claims 43 and 44 Define Heating That Is Not Disclosed In The Prior Art.

The Van Gorp patent does not disclose the method of heating the preserved mucosa tissue as defined in claims 43 and 44. Claim 43 and 44 depend from claim 36 and read as follows:

43. The method of claim 36, the method further comprising:
heating the mucosa tissue to a temperature in the
range of about 50-105°C prior to combining the
peroxide-containing compound and the mucosa
tissue.
44. The method of claim 36, the method further comprising:
heating the mucosa tissue to a temperature in the
range of about 65-75°C prior to combining the
peroxide-containing compound and the mucosa tissue.

Claims 43, and 44 thus each require heating the mucosa tissue prior to combination of the hydrogen peroxide or peroxide-containing compound with the mucosa tissue and thus each require a combination of heating and preservative addition. In the present Office Action, the Examiner relies only on the Van Gorp patent for the disclosure that *allegedly* includes both preservative addition and heating:

Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claims 24, 43 and 44.

(Page 3, second complete paragraph, of Office Action mailed on July 2, 2002). However, the heating referred to by the Examiner is a *physical* treatment that is specified in the Van Gorp patent as an alternative to the described chemical treatment:

When the raw material is transported or stored for a period of time before processing, it is preferably treated by physical or chemical means to inhibit bacterial growth. Physical means include temperature elevation into the range between 50 degrees C. and 95 degrees C. Chemical means include the use of a bacteriostat or bacteriocide.

(Column 4, lines 17-22, of the Van Gorp patent). (Emphasis added). Clearly, the Van Gorp patent calls for heating or preservative addition and does not teach, suggest, or disclose that the heating and preservative addition both occur in some combination. On the other hand, claims 43 and 44, as is clear from reading claims 43 and 44 above, each require *both* heating and preservation agent

addition. Furthermore, neither the remainder of the Van Gorp patent nor the Balslev patent includes any teaching, suggestion, or disclosure that both heating and preservative addition be employed or that the substrate be heated to the temperatures in the range of those specified by claims 43 and 44 prior to adding a chemical preservative.

In the Advisory Action mailed on October 17, 2002, the Examiner stated:

Applicant's assessment that the heating and preservative addition steps of Van Gorp are mutually exclusive, is incorrect. By disclosing that either heating or preservative addition is suitable to ensure low microorganism counts in the mucosa preparations, Van Gorp clearly provides a beneficial result as well, thereby rendering such practice obvious. Note that these methods of spoilage prevent[ion] sic are extremely well known and extremely old in the art of preservation. Moreover, if the combination of steps is required or critical for patentability, it should appear in the independent claim, not in one of the dependent claims.

(Advisory Action mailed on October 17, 2002, pages 2-3).

The Van Gorp patent clearly states the heating or chemical treatment is an either-or proposition. There is no teaching in the cited art that the heating and chemical treatment to preserve mucosa tissue should be done in series. A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983). Here, the Examiner, in the course of improperly attempting to piece together elements using the claimed invention as a road map, also improperly tries to disregard the literal teaching of the reference as a whole. Nonetheless, when considering the entirety of the Van Gorp patent, the Van Gorp patent clearly teaches only the separate use of heating or chemical treatment in the course of preserving the mucosa, contrary to the requirements of both claims 43 and 44.

Claims 43 and 44 are each believed allowable. Therefore, Applicants respectfully request that the Board reconsider and reverse the Examiner's rejection of claims 43 and 44 under 35 U.S.C. §103 based upon the Van Gorp and Balslev patents and that claims 43 and 44 be allowed.

D. Claims 48 and 50 Define Details About Contacting The Hydrolyzed Mucosa Product With A Protein-Containing Material That Is Not Disclosed In The Prior Art.

The Examiner improperly rejected claims 48 and 50 as allegedly being obvious over the Van Gorp patent in view of the Balslev patent. Claims 48 and 50 read as follows:

48. The method of claim 46, the method further comprising contacting the hydrolyzed mucosa product with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reduce enzymatic activity of the hydrolyzed mucosa product.

50. The method of claim 49, the method further comprising contacting the hydrolyzed mucosa tissue with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reducing enzymatic activity of the hydrolyzed mucosa tissue.

Claims 48 and 50 thus each require combination of a hydrolyzed protein substance with a protein-containing substance to hydrolyze protein contained in the protein-containing substance, while reducing the enzymatic activity of the hydrolyzed mucosa product. There is nothing in the Van Gorp patent, the Balslev patent, or the Oles patent that teaches, suggests, or otherwise make obvious the combination of a hydrolyzed protein substance with a protein-containing substance to hydrolyze protein contained in the protein-containing substance, while reducing the enzymatic activity of the hydrolyzed mucosa product, as claims 48 and 50 each require. In fact, the Van Gorp patent instead discloses interrupting the enzymatic action by raising the temperature of the hydrolyzed solution to about 90°C for about 30 minutes. (Col. 5, lines 3-4).

In response to the Applicant's argument, the Examiner responded as follows:

Applicant's argument regarding Van Gorp's failure to disclose hydrolysis of the mucosa ignores the plain disclosure of the reference. The title of the Van Gorp patent is "Protein Hydrolysate Derived From Mucosa Tissue." The abstract states that mucosa tissue is hydrolyzed with a proteolytic enzyme. Enzymes are protein-containing materials. Because the claimed starting material is contacted with the claimed treating agent, the result, reduction of enzymatic activity, must necessarily be the same. If the result is not

the same, the difference must be due to some aspect not currently recited in the claims.

(Advisory Action Mailed on October 17, 2002, page 3).

The Examiner's argument is flawed in that claims 48 and 50 each require: "contacting hydrolyzed mucosa product with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reduce enzymatic activity of the hydrolyzed mucosa product." (Emphasis added). The Van Gorp patent teaches hydrolyzed mucosa product with some residual enzymatic activity (residual "protein-containing material," in the words of the Examiner), since the Van Gorp patent teaches a need to interrupt residual enzymatic action by raising the temperature of the hydrolyzed mucosa product solution to about 90°C for about 30 minutes. (Col. 5, lines 3-4).

The Examiner apparently alleges the enzyme itself is the secondary protein containing material in the Van Gorp process that is contacted with the hydrolyzed mucosa product. However, this argument is flawed on at least two grounds. First, the Van Gorp patent does not teach any secondary addition of enzymes ("protein-containing material," in the words of the Examiner) to the hydrolyzed mucosa product. Secondly, the Examiner has not produced any evidence that the enzymes ("protein-containing material," in the words of the Examiner) are hydrolyzed (i.e. self destructed) in the Van Gorp system, or in any other enzymatic hydrolysis system, for that matter. Indeed, in Applicant's experience, the enzymes ("protein-containing material," in the words of the Examiner) are not actually hydrolyzed but are instead used to hydrolyze other materials (i.e. the substrate) during enzymatic hydrolysis. Ultimately, there simply is no teaching, suggestion motivation, or disclosure in any of the references relied upon by the Examiner that the enzymes ("protein-containing material," in the words of the Examiner) are hydrolyzed (i.e. self destructed) in the Van Gorp system. Therefore, claims 48 and 50 are not made obvious by the Examiner's combination of details from the Van Gorp patent in view of details from the Balslev patent.

A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983). Here, the Examiner, in the course of improperly attempting to piece together elements using the claimed invention as a road map, also improperly

tries to disregard the literal teaching of the reference as a whole in the course of apparently alleging, without providing any evidentiary support, that the Van Gorp patent teaches self-hydrolysis (i.e. self destructing) by the enzymes in the Van Gorp system. Nonetheless, when considering the entirety of the Van Gorp patent, the Van Gorp patent clearly does not teach anything about self-hydrolysis (i.e. self destructing) by the enzymes in the Van Gorp system. Consequently, the Van Gorp patent does not teach, suggest, motivate, or disclose contacting the hydrolyzed (via enzymatic hydrolysis) mucosa product with a secondary protein-containing material, as claims 48 and 50 each require.

Claims 48 and 50 are each believed allowable. Therefore, Applicants respectfully request that the Board consider and reverse the Examiner's rejection of claims 48 and 50 under 35 U.S.C. §103 based upon the Van Gorp, Balslev, and Oles patents and that claims 48 and 50 be allowed.

E. Claims 37-52 Are Allowable Because Each Claim Depends From Allowable Independent Claim 36.

Claims 37-52 were rejected as being obvious based upon details disclosed in the Van Gorp patent in view of details disclosed in the Balslev patent. Claims 37-52 are dependent upon independent claim 36. Claim 36 is allowable and non-obvious, see §§ III A and B. Because claim 36 is allowable and non-obvious, claims 37-52, which depend from claim 36, are also allowable and non-obvious. Applicants respectfully request the Board consider and reverse the Examiner's obviousness rejection of claims 37-52 under 35 U.S.C. §103 based upon the Van Gorp, Balslev, and Oles patents and that claims 37-52 be allowed.

IV. The Van Gorp Patent In View of The Oles Patent Does Not Teach, Suggest or Make Obvious The Invention Of The Present Application As Defined In Claims 53 And 54.

A. The Examiner Impermissibly Relied On Hindsight Reconstruction When Alleging Claim 53 Is Obvious.

The Examiner clearly used the features defined in claim 53 as a map to find and combine details when alleging the present invention, as defined in claim 53, is obvious. It is

improper to use hindsight reconstruction to pick and choose among isolated disclosures in the prior art. *In re Fine*, 5 U.S.P.Q.2d at 1600. An Examiner should forget the invention at issue when considering whether it would be obvious to modify a prior art disclosure. *W. L. Gore*, 220 U.S.P.Q. at 312-13. The Examiner improperly relied on hindsight reconstruction when combining details from the Oles patent with details from the Van Gorp patent to arrive at the invention defined in claim 53.

The Balslev patent was cited for the alleged proposition that hydrogen peroxide is a well known preservative. Since neither independent claim 53 nor dependent claim 54 include hydrogen peroxide as an element, the Balslev patent is not relevant to the non-obviousness analysis of claims 53-54. As such, the Balslev patent will not be discussed in § IV of this Brief.

Admittedly, the Van Gorp patent is relevant prior art because the Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. On the other hand, the method disclosed in the Van Gorp patent, standing alone, does not fully disclose the present invention, as defined in claim 53 because the Van Gorp patent does not disclose combining the mucosa tissue with phosphoric acid to form an intermediate. The Oles patent does disclose the synergistic use of (1) phosphoric acid in combination with (2) acetic acid or another organic food acid as a preservative in the food art. However, the art of preserving mucosa tissue and food art are unrelated and there is no teaching in either patent that would lead to the Examiner's combination of references. Nonetheless, the Examiner chose to erroneously rely on the combination of details from the Van Gorp patent with details from the Oles patent in an attempt to allege claim 53 is obvious and therefore allegedly unpatentable.

There is no connection between the Van Gorp patent and the Oles patent except for the invention defined in claim 53. The Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. On the other hand, the Oles patent discloses food products that are preserved without use of artificial preservatives by the synergistic effect of (1) acetic acid or other organic acids in combination with (2) phosphoric acid. (Col. 2, lines 31-34). The Examiner's combination of details from these references must fail to avoid improper hindsight reconstruction.

One skilled in the art would not attempt to combine process details concerning the industrial preservation of pig guts, where proteins of the pig guts are later broken down with an enzyme by hydrolysis, with details about formation of a food stuff, such as mayonnaise and salad dressing. Instead, the Examiner picked and chose elements from entirely unrelated references in an attempt to remedy the deficiencies of the Van Gorp patent and find claim 53 obvious. The Examiner improperly used the features defined in claim 53 as a map to find and combine details when alleging the present invention, as defined in claim 53, is obvious. Therefore, the Examiner's rejection of claim 53 as allegedly being obvious should be reversed. The arguments presented above in this § IV. A are equally applicable to claim 22 that specifies phosphoric acid. Therefore, the Examiner's rejection of claim 22 as allegedly being obvious is also improper and should be reversed.

B. There Is No Teaching Or Suggestion In The Prior Art That Would Lead One Skilled In The Art To Combine The Cited References.

The Examiner alleged claim 53 was unpatentable over the Van Gorp patent in view of the Oles patent. Nonetheless, despite the Examiner's rejection, the Van Gorp and Oles patents, either separately or in any combination, do not teach, suggest, disclose, or make obvious the invention of the above-identified application, as defined in claims 53 and 54. Claim 53 reads as follows:

A method of treating mucosa tissue, the method comprising adding phosphoric acid to the mucosa tissue to form an intermediate.

The Examiner rejected claim 53 in an Office Action mailed on January 11, 2002. The Examiner alleged the following:

Van Gorp discloses a process wherein a mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. *See* col.4, lines 17-34 and 45-50. Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claim 24. Note further that because it contains the same material, mucosa, Van Gorp's preserved product would inherently have the same ash amount as recited in the claims.

Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. However, each of Oles (see, e.g., abstract) and Balslev (see e.g., abstract) make it clear that both phosphoric acid and peroxide were well known preservatives in food and/or pharmaceutical applications. Thus, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev would have functioned equivalently to the preservatives disclosed by Van Gorp, the artisan of ordinary skill would have been motivated to have substituted Oles' phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.

The Examiner improperly combined details from the Oles patent with details from the Van Gorp patent when alleging the invention defined in claim 53 is obvious.

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the **relevant** art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972)(emphasis added). In rejecting claim 53 as allegedly being obvious, the Examiner attempted to combine details from a patent disclosing preservation of pig tissues prior to hydrolysis of proteins from the pig tissues *with* details from a patent the Examiner admitted were part of the food art. The food art is not relevant to the preservation of proteins prior to hydrolysis. Therefore, for this initial reason, the Examiner's combination of references is improper.

The Examiner's simplistic attempt to justify the combination of details from the Van Gorp patent with details from the Oles patent hinges on the Examiner's so-called "well known preservative" theory. In essence, the Examiner's argues the Van Gorp patent discloses use of "well known preservatives" to preserve mucosa tissue. Similarly, according to the Examiner, the Oles patent allegedly also discloses "well known preservatives." Therefore, since only "well known preservatives" are employed in the three references, and all "well known preservatives" are allegedly

equivalent and substitutable for each other (apparently, no matter the application, per the Examiner), all “well known preservatives” can be substituted for each other between the three references.

As convenient as the “well known preservative” theory is, it does not conform to established law. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992).

There is no teaching or suggestion in the Van Gorp patent disclosure to use any preservative other than an oxygen, an antioxidant, or, in low acidity environments, calcium propionate. (Col. 4, lines 22-35). In this regard, the Van Gorp patent principally mentions use of sodium metabisulfite as an oxygen scavenger, while also referencing use of calcium propionate, BHT, and BHA as alternatively acceptable preservatives. (Col. 4, lines 25-34).

The Examiner attempted to make the combination of references with an unsubstantiated, speculative statement that: “the claimed substitution of well known preservatives for those used in Van Gorp must be an obvious substitution of one known equivalent for another.” The Examiner must provide reasons why the Examiner’s combination of references is permitted. The Examiner failed to provide any reason except for the speculative, simplistic, and self-serving “well known preservative” theory.

While the Examiner provided no factual bases for the improper combination of references, Applicant submitted evidence to the Examiner showing that most chemical agents have only very specific food preservation actions and functionalities and therefore must be carefully matched to the particular preservation action desired. Jay, James M., Modern Food Microbiology, pages 259-296 (Van Nostrand Reinhold 1986) (attached as Exhibit D). Indeed, some chemical agents are active only against molds while other chemical agents are active only against yeast and still other agents are active only against certain bacteria. *Id.* Furthermore, most chemical agents require specific conditions of pH, moisture, and/or temperature to function effectively as preservatives. *Id.*

The details provided throughout the Exhibit D reference demonstrate there is no support whatsoever for the Examiner's allegation that the Oles phosphoric acid "would have functioned equivalently to the preservatives disclosed by Van Gorp" and therefore "must be considered an obvious substitution of one known equivalent preservative for another." Indeed, the mere fact that the Oles patent relies on a synergistic combination of acidifying agents (a combination of (1) acetic acid or other organic acid and (2) phosphoric acid), whereas the Van Gorp patent principally relies on an oxygen-scavenging stabilizer (while also mentioning anti-oxidants and, for low acidity environments, calcium propionate) demonstrates the wide difference in operating function between the preservatives of the Van Gorp patent and the preservatives of the Oles patent. There simply is no reasonable basis for believing an "artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles . . . that phosphoric acid . . . would have functioned equivalently to the preservatives disclosed by Van Gorp" and would therefore "have been motivated to have substituted Oles' phosphoric acid . . . for the preservatives disclosed by Van Gorp," despite the Examiner's conclusory allegation to the contrary.

Furthermore, the Examiner's reasoning is contrary to the holding in *In re Mills*. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). The Van Gorp patent principally suggests use of oxygen scavengers as preservatives, while also mentioning antioxidants and, for low acidity environments, calcium propionate. The Van Gorp patent does not suggest incorporation of an acidifier (such as phosphoric acid) in the process disclosed in the Van Gorp patent. The Examiner has not provided any proof that phosphoric acid serves as an oxygen scavenger or is otherwise equivalent in function to any of the preservatives disclosed in the Van Gorp patent. There is no teaching in the Van Gorp patent that suggests the desirability of incorporating the preservatives disclosed in the Oles patent into the process of the Van Gorp patent.

The Examiner improperly combined details from the Oles patent with details from the Van Gorp patent when alleging the invention defined in claim 53 is obvious. The mere fact that the preservatives disclosed in the Oles patent **may** be used in the Van Gorp patent does not necessarily render claim 53 unpatentable as allegedly being obvious. The Examiner has not met his burden of showing a teaching or suggestion to combine details from the two different references; therefore the Examiner's obviousness rejection should be reversed.

Furthermore, the Examiner mischaracterizes the preservative disclosed in the Oles patent. The Oles patent clearly and plainly discloses a synergistic effect between two different components: (1) phosphoric acid and (2) acetic acid or another organic food acid. "The food compositions of the present invention contain a synergistic combination of acetic acid or other organic food acid and phosphoric acid." (Col. 2, lines 31-34). The Oles patent teaches preserving foods with an organic acid and phosphoric acid, not phosphoric acid alone. Claim 53 defines the invention as a method of treating mucosa tissue where the method comprises "adding phosphoric acid to the mucosa tissue to form an intermediate." Even though claim 53 does employ the open "comprising language, claim 53 specifies that it is the phosphoric acid in combination only the mucosa tissue that forms the preserved mucosa (intermediate of claim 53). The invention that claim

53 defines as a preserving agent includes phosphoric acid but does not include another ingredient working in synergy with the phosphoric acid, as the Oles patent requires.

The Oles patent does not teach the individual use of phosphoric acid, as claim 53 specifies, as a preserving agent. Rather the Oles patent discloses the use of a combination of (1) phosphoric acid with (2) another organic acid that collectively and synergistically serves as a preserving agent. The Examiner must take each reference for what it teaches as a whole and cannot pick and choose elements from a reference without regard to the overall teaching of the reference. This reference fails to teach the details th Examiner cites the reference as teaching. Therefore, the Examiner's combination of details from the Van Gorp patent with details from the Oles patent does not make claim 53 obvious.

For the above stated reasons, incorporation of the preservatives disclosed in the Oles patent into the process disclosed in the Van Gorp patent is improper. There is no teaching or suggestion in the cited references that would lead one skilled in the art to combine the references. In fact, the references actually teach away from the Examiner's suggested combination. The obviousness rejection of claim 53 based upon the Van Gorp patent in view of the Oles patent is improper and should be reversed. The arguments presented above in this § IV. B are generally applicable to claim 22 that specifies phosphoric acid, as well. Therefore, the obviousness rejection of claim 22 based upon the Van Gorp patent in view of the Oles patent is also improper and should be reversed.

C. Claim 54 Is Allowable Because Claim 54 Depends From Allowable Independent Claim 53.

Claim 54 was rejected as allegedly being obvious based on the Examiner's combination of details from the Van Gorp patent with details from the Oles patent. Claim 54 is dependent upon independent claim 53. Claim 53 is allowable and non-obvious, see §§ IV A and B. Because claim 53 is allowable and non-obvious, claim 54, which depends from claim 53, is also allowable and non-obvious. Applicants respectfully request that the Board reconsider and reverse the obviousness rejection under 35 U.S.C. §103 based upon the Van Gorp patent and the Oles patent and that claim 54 be allowed.

V. Claim 42 Is In Allowable Form And Is Definite.

The Examiner erroneously rejected claim 42 as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention." In support of this rejection, the Examiner stated:

Secondly, it is confusing what the claim is intending to recite since it recites addition of a product to a composition, but then recites that the added product must become undetectable.

(Office Action Dated July 2, 2002, pages 2-3). Despite the Examiner's comments, claim 42 is believed to be definite within the meaning of the second paragraph of 35 U.S.C. §112.

Claim 42 reads as follows:

The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being undetectable when the concentration of the peroxide-containing compound remaining in the mucosa product is determined using KMnO_4 titration.

The Examiner also commented upon claim 42 in an Advisory Action stating as follows:

With the rejection under §112, second paragraph, it is respectfully submitted that claim 42 still does not make sense. While it may be true that eventually the hydrogen peroxide added to the mucosa decomposes, it is simply impossible to add peroxide to the mucosa and then detect no peroxide immediately thereafter. Because of the impossibility, as drafted, the claim makes no sense.

(Advisory Action mailed on October 17, 2002, page 2).

The Examiner's allegation requires consideration of the basis for claim indefiniteness. The second paragraph of 35 U.S.C. §112 states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Thus, the second paragraph of 35 U.S.C. §112 merely requires that the claims set forth out and circumscribe "a particular area with a reasonable degree of precision and particularity." Buell v. Beckestrom, 22 U.S.P.Q.2d 1128, 1133 (P.T.O. Bd. Pat. App. & Int'f. 1992); In re Miller, 169 U.S.P.Q. 597, 599 (C.C.P.A. 1971).

The definiteness requirement of the second paragraph of 35 U.S.C. § 112 is concerned with whether one of ordinary skill in the art will reasonably be able to determine if particular subject matter falls within the scope of a particular claim. Conversely, if one of ordinary skill in the art would reasonably be able to determine if particular subject matter falls within the scope of the claim, that claim is definite in accordance with the definiteness requirement of the second paragraph of 35 U.S.C. § 112. In re Skoll, 187 U.S.P.Q. 481, 482 (C.C.P.A. 1975); In re Mercier, 185 U.S.P.Q. 774, 780 (C.C.P.A. 1975) ("[I]f one can determine whether a particular catalytic process for splitting acetals and hemi-acetals is or is not within the scope of a claim, the claim fulfills its purpose as a definition."); In re Miller, 169 U.S.P.Q. 597, 599 (C.C.P.A. 1971) (If those skilled in the art can tell whether any particular PTFE powder is or is not within the scope of claim, the claim fulfills its purpose as a definition.").

Here, one seeking to determine if particular subject matter meets claim 42 would, in addition to considering the details of claim 36, need to determine if the particular subject matter entails "mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product," as claim 42 requires, and then additionally need to determine the concentration of the peroxide-containing compound remaining in the mucosa product. If the concentration of the peroxide-containing compound remaining in the mucosa product, when determined using KMnO_4 titration, is not "undetectable" (i.e. is "detectable") or if the particular subject matter does not entail "mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product," as claim 42 requires, then the person knows the particular subject matter falls outside the literal scope of claim 42. If, on the other hand, the concentration of the peroxide-containing compound remaining in the mucosa product, when determined using KMnO_4 titration, is "undetectable" and the particular subject matter does entail "mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product," as claim 42 requires, then the person knows the particular subject matter falls within the literal scope of claim 42.

The Examiner's comments about confusion regarding "what the claim is intending to recite" merely reflects the existence of a reaction, when practicing the invention in accordance with claim 42, that reduces the concentration of the peroxide-containing compound remaining in the

mucosa product below the detection limit of the KMnO_4 titration procedure. One skilled in the art would understand from the language of claim 42 that hydrogen peroxide is not detectable because a chemical reaction occurs between the mucosa tissue and the hydrogen peroxide immediately upon addition of the hydrogen peroxide. Claim 42 does not include any numeric limit on the amount of hydrogen peroxide that is added, beyond the literal requirement that some hydrogen peroxide be added; therefore, a minuscule amount of hydrogen peroxide could be added to mucosa tissue, react with the mucosa tissue, and become undetectable immediately thereafter and fall within the scope of claim 42.

The definiteness requirement of the second paragraph of 35 U.S.C. §112 does not require that one of ordinary skill in the art understand why a claimed result occurs. Instead, the definiteness requirement of the second paragraph of 35 U.S.C. §112 is merely concerned with whether one of ordinary skill in the art will reasonably be able to determine if his subject matter falls within or outside the scope of a particular claim. Skoll, 187 U.S.P.Q. at 482; Mercier, 185 U.S.P.Q. at 780. As explained in the previous paragraph, there is no reason to believe one of ordinary skill in the art would be incapable of understanding the requirements of claim 42 and making this determination. Consequently, claim 42 is believed definite in accordance with the second paragraph of 35 U.S.C. §112.

Claim 42 is believed allowable. Therefore, Applicants respectfully request that the Examiner's rejection of claim 42 under the second paragraph of 35 U.S.C. §112 be reversed and that claim 42 be allowed.

VI. Conclusion.

For the foregoing reasons the Examiner erred in rejecting claims 21-27 and 36-54. Reconsideration and reversal of the rejections of claims 21-27 and 36-54 accompanied by allowance of claims 21-27 and 36-54 are respectfully requested.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: January 6, 2003

By Philip F. Fox
Philip F. Fox, Reg. No. 38,142
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

APPENDIX A**CLAIMS**

21. A method for preserving mucosa tissue comprising mixing a quantity of mucosa tissue with a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid to yield the preserved mucosa tissue.
22. The method of claim 21, wherein said preserving agent is phosphoric acid, and said mixing step comprises adjusting the pH of the mucosa tissue with phosphoric acid to about 2-4.
23. The method of claim 21, wherein said preserving agent is hydrogen peroxide, and said mixing step comprises mixing less than about 1% by weight of hydrogen peroxide with said mucosa tissue, said percent by weight hydrogen peroxide being based upon the weight of the mucosa tissue taken as 100% by weight.
24. The method of claim 21, wherein said preserving agent is hydrogen peroxide, and further including the step of heating said mucosa tissue to a temperature of from about 50-105°C prior to said mixing step.
25. The method of claim 21, wherein said preserving agent is hydrogen peroxide, and said preserved mucosa tissue has an ash content of less than about 10% by weight, based upon the total weight of the preserved mucosa tissue as 100% by weight.
26. The method of claim 21, wherein said preserved mucosa tissue has a standard plate count of less than about 20,000 cfu/g about seven days after said preserving step.
27. The method of claim 21, wherein said preserved mucosa tissue has an *E. Coli* count of less than about 10 cfu/g about seven days after said preserving step.
36. A method of treating mucosa tissue, the method comprising combining the mucosa tissue and a peroxide-containing compound to form an intermediate.
37. The method of claim 36, wherein the peroxide-containing compound is hydrogen peroxide.
38. The method of claim 36, wherein the concentration of the peroxide-containing compound in the intermediate is initially less than about 1% by weight, based upon the total weight of the mucosa tissue and the peroxide-containing compound being 100% by weight.
39. The method of claim 38, wherein the concentration of the peroxide-containing compound in the intermediate is initially less than about 0.5% by weight, based upon the total weight of the mucosa tissue and the peroxide-containing compound being 100% by weight.

40. The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being less than about 0.04% by weight, based upon the total weight of the mucosa product being 100% by weight.
41. The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being less than about 0.01% by weight, based upon the total weight of the mucosa product being 100% by weight.
42. The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being undetectable when the concentration of the peroxide-containing compound remaining in the mucosa product is determined using KMnO_4 titration.
43. The method of claim 36, the method further comprising:
heating the mucosa tissue to a temperature in the range of about 50-105°C prior to combining the peroxide-containing compound and the mucosa tissue.
44. The method of claim 36, the method further comprising:
heating the mucosa tissue to a temperature in the range of about 65-75°C prior to combining the peroxide-containing compound and the mucosa tissue.
45. The method of claim 36 wherein the mucosa tissue comprises substantially non-hydrolyzed mucosa tissue.
46. The method of claim 45 wherein the intermediate is a treated mucosa product, the method further comprising hydrolyzing the treated mucosa product to form a hydrolyzed mucosa product.
47. The method of claim 46 wherein the hydrolyzed mucosa product comprises heparin, the method further comprising extracting heparin from the hydrolyzed mucosa product.
48. The method of claim 46, the method further comprising contacting the hydrolyzed mucosa product with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reduce enzymatic activity of the hydrolyzed mucosa product.
49. The method of claim 36 wherein the mucosa tissue comprises hydrolyzed mucosa tissue.

50. The method of claim 49, the method further comprising contacting the hydrolyzed mucosa tissue with a protein-containing material under conditions effective to hydrolyze at least some protein of the protein-containing material and thereby reducing enzymatic activity of the hydrolyzed mucosa tissue.

51. The method of claim 36 wherein the intermediate is a treated mucosa product, the treated mucosa product having an ash concentration of less than about 10% by weight, based upon the total weight of the treated mucosa product being 100% by weight.

52. The method of claim 51, wherein the treated mucosa product has an ash content of less than about 7% by weight, based upon the total weight of the treated mucosa product being 100% by weight.

53. A method of treating mucosa tissue, the method comprising adding phosphoric acid to the mucosa tissue to form an intermediate.

54. The method of claim 53 wherein the intermediate initially has a pH in the range of about 2-4 after the phosphoric acid is added to the mucosa tissue.

APPENDIX B
REFERENCES CITED (Copies are Attached)

Exhibit A: U.S. Patent No. 5,607,840 (the Van Gorp patent)

Exhibit B: U.S. Patent No. 4,438, 100 (the Balslev patent)

Exhibit C: U.S. Patent No. 4,145,451 (the Oles patent)

Exhibit D: Jay, James M., Modern Food Microbiology, pages 259-296 (Van Nostrand Reinhold 1986)

Exhibit E: Merriam-Webster Dictionary Definition of OXIDIZE from www.m-w.com (12-18-02)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named

Inventor : John H. Lee et al.

Appln. No. : 09/392,243

Filed : September 9, 1999

Title : PROCESSES FOR MAKING PROTEIN
HYDROLYSATES FROM ANIMAL
PEPTONE AND FOR PRESERVING
MUCOSA

Docket No. : LL11.12-0073

Group Art Unit: 1651

Examiner: F. Prats

EXHIBIT A OF APPENDIX B IN BRIEF FOR APPELLANT

U.S. Patent No. 5,607,840 (the Van Gorp patent)

United States Patent [19]

Van Gorp et al.

[11] Patent Number: 5,607,840

[45] Date of Patent: Mar. 4, 1997

[54] PROTEIN HYDROLYSATE DERIVED FROM MUCOSA TISSUE

[75] Inventors: Cornelius L. Van Gorp, Lebanon, Ohio; Frederick Vosburgh, Fort Wayne, Ind.; Robert L. Schubert, II, Monroe, Ohio

[73] Assignees: Celsus, Inc., Cincinnati, Ohio; Consolidated Nutrition, L.C., Omaha, Nebr.

[21] Appl. No.: 225,427

[22] Filed: Apr. 8, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 983,810, Nov. 30, 1992, abandoned.

[51] Int. Cl.⁶ C12P 21/06; A23L 1/305; A23J 3/30; A61K 38/01

[52] U.S. Cl. 435/68.1; 426/56; 426/657; 426/801; 426/807; 424/520; 435/262; 435/101; 514/2; 514/56; 530/416

[58] Field of Search 435/68.1, 262, 435/101; 426/656, 657, 56, 801, 807; 424/520; 514/2, 56; 530/416

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Primary Examiner—David M. Naff

Attorney, Agent, or Firm—Baker & Daniels

[57] ABSTRACT

A protein hydrolyzate is produced from mucosa tissue of pigs, cattle or sheep by providing an aqueous mixture of the tissue, hydrolyzing the tissue with a proteolytic enzyme at a salt concentration of less than 0.1 molar to produce a digest solution containing a protein hydrolyzate and polyanions including heparin, adsorbing the polyanions on an anion exchange resin, recovering the anion exchange resin containing adsorbed polyanions to provide a digest solution containing less than 2.9 u/ml residual heparin and recovering the protein hydrolyzate from the digest solution by screening or dehydration. The protein hydrolyzate contains less than 15% ash, between 9.5 and 11.5% total Kjeldahl nitrogen and between 5.0 and 7.0% alpha amino nitrogen. The protein hydrolyzate may be used in nutritional formulations such as to promote weight gain in newly weaned livestock and in medical formulations such as peritoneal dialysis fluids and formulations for use in enteral and parenteral nutrition.

7 Claims, No Drawings

PROTEIN HYDROLYSATE DERIVED FROM MUCOSA TISSUE

This is a continuation of application Ser. No. 07/983,810,
filed Nov. 30, 1992, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a protein hydrolysate derived from animal tissue having an endothelial or mucosal component (hereafter "mucosa"), a process for its preparation, and the use of such a protein hydrolysate.

Protein hydrolysate by definition consists of a mixture of amino acids and short chain peptides obtained by the hydrolysis of various animal and vegetable proteins. Protein hydrolysates (also known as "peptones") are used as sources of amino acids, seasoning agents and in nutrition, among other things.

For both economic and environmental reasons, productive use is now being made of an increasing percentage of the waste material generated as a result of the slaughter of animals, such as livestock. A major use of livestock waste or other by-products (livestock "offal") is in the production of the blood anti-coagulant heparin.

It has been estimated that over 90% of the heparin currently used as a blood anti-coagulant is obtained from porcine intestinal mucosa. An aqueous solution containing the mucosa from the livestock offal is chemically (acid or alkaline) or enzymatically hydrolyzed, and the heparin is extracted from the hydrolyzed mucosa by well-established techniques, such as selective sorption using an ion exchange resin. The solution containing the digested tissues includes high concentrations of salt. This high concentration of salts in the digest solution prevents constituents other than certain anionic and polyanionic materials (such as heparin) from sticking to the resin during the sorption of these materials. Although the cost of such resin can be high, an advantage of this process is that it requires only a minimal amount of resin, since only enough resin is required to selectively remove the desired anionic or polyanionic materials from the digest solution.

The mucosa and the digest solution also generally contain an additional salt component. This additional salt component is introduced into the solution in the form of an oxygen scavenger, bacteriostat or bactericide, typically sodium bisulfite, added to stabilize the raw material and to prevent bacterial growth.

The high residual concentration of salt in the digest solution renders the un-sorbed portion of the digest, which includes most of the proteins, largely useless for most practical purposes. These salt and sulfite levels not only make this protein sidestream inedible, but also potentially toxic for prolonged usage such as in agriculture as a source of nitrogen. The sidestream may also be toxic to those animals or humans allergic to sulfites.

The heparin-depleted digest solution is typically discarded or spread on farm land, since cost-effective ways have not been found to separate the organic components in the solution from the dissolved salt. The discarded solution, however, includes many high quality proteins in the form of protein hydrolysate. Rather than discarding these proteins, it is desirable to utilize them as a source of protein for human or animal nutrition. Additional use can be made of the proteins in microbial nutrition, such as vat fermentation.

Waste disposal costs of solutions of animal waste products continue to increase, and environmental regulations

govern the manner in which high BOD materials, such as the heparin-depleted digest, may be disposed. The costs associated with disposal add not only to the cost of processing the livestock, but also to the cost of the heparin produced by this process.

Protein hydrolysates may be produced by either chemical or enzymatic methods. In acid hydrolysis, strong acids at elevated temperatures are used to break the glycosidic bond in the protein molecule. This relatively harsh treatment can result in damage to the heparin as well as some loss of essential amino acids. The treatment can also result in undesirable side reactions. Similarly, alkaline hydrolysis requires fairly extreme conditions for producing this reaction. Furthermore, the large amount of residual acid or alkali in the hydrolysate must be neutralized. This neutralization increases the salt content of the hydrolysate, and thereby further limits its potential use in nutritional formulations seeking minimum salt content.

Enzyme hydrolysis is an effective alternative to chemical treatment. This process is mild in comparison to acid or alkali hydrolysis. Additionally, the inherent specificity of several proteolytic enzymes can control the nature and extent of hydrolysis, and thus the functional properties of the end product. An important use of enzymatically hydrolyzed proteins is in human nutrition. Additionally, the proteins may be used in medical nutrition for undernourished persons, or those persons unable to properly digest and absorb whole protein. For example, it has been postulated that in cases of severe pancreatic insufficiency or malabsorption, that amino acids are better absorbed from hydrolyzed protein than from intact protein.

An initial source of pre-digested protein was milk, which has drawbacks such as poor palatability and high cost. Recently, individual crystalline amino acids have been formulated to mimic the amino acid profile of the protein hydrolysate obtained by hydrolysis of casein. Medical studies, however, have shown that di- and tripeptides such as can be produced by protein hydrolysis, are absorbed through the intestinal mucosa more effectively than the individual crystalline amino acids. Aside from the potential danger of allergic reactions to such crystalline amino acids, often produced by fermentation, such protein hydrolysate formulations are extremely expensive and out of reach for the world population at large.

Nutritional uses of the protein hydrolysate of the present invention include such specialty feeds as milk replacers for calf, piglet and other weaning mammals; protein extender for animal feed; and as an amino acid supplement, flavor or protein enhancer for human food and pet food. Research has shown that the high ash in peptone, or hydrolysate, obtained by traditional processes, significantly depresses appetite and weight gain at moderate inclusion rates. See, e.g. *Journal of Dairy science*, 75(1): 267; 1992, incorporated herein by reference. Medicine to which this invention may be applied includes total parenteral nutrition, peritoneal dialysis fluid as an alternative to glucose, and as a protein extender in enteral nutrition. Additional use may be found in microbial nutrition for vat fermentation.

British Patent 992,201 describes the conventional procedure for producing heparin described above. The procedure involves the addition of cross-linked copolymers with quaternary functional groups to a heparin-containing digest, using an alkali, alkali earth metal, or ammonium salt as a catalyst. At least 0.1 mole of a dissolved salt must be present. The recommended salt is sodium chloride. This patent focuses on the isolation of heparin and certain other anionic

and polyanionic impurities from the remaining constituents in the digest. The isolation of protein hydrolysates, in a contaminated form in the digest, is not addressed in this patent. The examples in the patent teach a 0.5 molar salt concentration to accomplish the separation of the heparin, 5 representing the midpoint in a claimed range of 0.1-1.0 molar.

After the anion exchange resin-heparin copolymer is harvested according to the procedure described in the British patent, the resulting protein-containing sidestream contains not only sodium chloride as a contaminant, but also the original sodium metabisulfite stabilizer, and the various biological materials (including protein hydrolysate) present in the raw materials that are not sorbed by the resin. These impurities left in the protein mother liquor after the harvesting of the resin-heparin copolymer render it largely useless for most practical applications.

Another commercial process presently in use for the production of heparin is based on the purification procedure described in British Patent 889,648. This process consists of treating a heparin-containing digest, which has previously been filtered to clarity, with 2 to 5% of salt and sufficient water soluble quaternary ammonium salt to selectively precipitate substantially all the heparin, but insufficient to precipitate other animal components. The protein sidestream of this process also contains a high percentage of salt. Furthermore, most quaternary ammonium salts are effective bacteriocides thus rendering any resulting protein unsuitable for fermentation. Process waste waters containing quaternary ammonium salts also have an adverse effect on municipal sewage operations.

A common thread of the two processes described above is that only limited use may be made of the heparin-depleted protein sidestream due to its high residual salt content. A need exists for a process for treating animal tissue, and particularly livestock offal, that minimizes the waste of that tissue and enables beneficial use to be made of the protein hydrolysate that may be derived from the tissue.

SUMMARY OF THE INVENTION

The aforementioned need is met by the present method for preparing a protein hydrolysate and by the protein hydrolysates prepared by the method. The protein hydrolysates of the present invention are derived from animal tissue having endothelial components. According to the present invention, a protein hydrolysate in virtually pure form may be produced by treating digested mucosa tissue with less than 0.5 molar salt, and preferably less than 0.1 molar the salt being an alkali metal salt, an alkali earth metal salt, an ammonium salt of an acid, or a mixture thereof.

A sufficient amount of anion-exchange resin is used in the present invention to enable the adsorption of virtually all of the polyanion "impurities" in the digest, with the protein hydrolysate remaining in the digest. These impurities, which include heparin, are present as glycosaminoglycans, nucleic acids or other such entities in the starting material. The protein hydrolysate, thus isolated, is void of these impurities. The protein hydrolysate is also void of the inherent disadvantages of the protein hydrolysate produced by conventional processes. A protein hydrolysate produced by the method of the present invention may have the following properties, on a dried basis: less than 15% ash; between 9.5 and 11.5% total Kjeldahl nitrogen; and between 5.0 and 7.0% α amino nitrogen. In addition, the hydrolysate may have an amino acid profile having the following properties

on a dried basis: between 4.5 and 6.0% glycine; between 5.5 and 7.0% lysine; between 0.5 and 2.5% methionine; between 1.5 and 3.5% serine; between 4.5 and 7.0% leucine; and between 10.0 and 12.5% glutamic acid.

DETAILED DESCRIPTION OF THE INVENTION

The raw material for use in the inventive process for producing protein hydrolysates is animal tissue having an endothelial or mucosal component (mucosa). Typical raw materials envisioned for use in the process are livestock by-products, including gastrointestinal, tracheal or bronchial tissues, or other offal or non-offal tissues. The process water of livestock or meat processing establishments may also serve as a raw material.

When the raw material is transported or stored for a period of time before processing, it is preferably treated by physical or chemical means to inhibit bacterial growth. Physical means include temperature elevation into the range between 50 degrees C. and 95 degrees C. Chemical means include the use of a bacteriostat or bacteriocide. The purity of the protein hydrolysate may be optimized by using mucosa tissue which has been stabilized with a minimal amount of a bacteriostat such as an oxygen scavenger. Sodium metabisulfite is an example of an oxygen scavenger that has been found suitable. Another suitable preservative is calcium propionate, a preservative which is generally recognized as safe (GRAS) in food, and therefore is not subject to the restrictions associated with the use of bisulfites in food for humans. Other suitable preservatives that may be utilized in certain applications include bacteriostats such as BHT and BHA, and antibiotics that are known to be suitable for animal feed applications.

A preferred source of the mucosa raw material is government inspected pork intestines. Additional sources of suitable raw material include, for example, intestinal mucosa, intestinal skin or adventitia, trachea, lung and liver of animals such as pigs, cattle or sheep. Prior to digestion, the raw material may initially be subjected to ultrafiltration or reverse osmosis to reduce the water and salt content of the tissue. This removed "tissue water" includes a certain amount of salt; therefore its removal prior to digestion reduces the salt content in the final product.

If the raw material is to be transported or stored, a stabilizer, such as 0.5% (w/v) sodium metabisulfite or, preferably, 0.5% (w/v) calcium propionate, is added; or the raw material is maintained at an elevated temperature between 55° C. and 90° C.

The raw material is then introduced into a vat for processing. The raw material may be extracted under nonproteolytic conditions of certain molecules that are functionally destroyed by enzymes, such as proteoglycans which may have different properties than the glycosaminoglycans left after digestion. An extracting salt, such as guanidine hydrochloride, is added. The extracted constituents and extracting salts are separated from the tissues in a conventional manner, such as by centrifuge or filtration.

The resulting mucosa tissue is then heated to 55° C. Optionally, the tissue may first be heat denatured at 90° C. The pH is adjusted to an appropriate level for the enzyme with an appropriate agent, such as liquid caustic soda. The particular pH level may differ depending on the characteristics of the particular enzyme used. Approximately 1.5 gram of enzyme per kilo mucosa tissue is then added to hydrolyze the tissue. Under constant agitation, hydrolysis is

continued for a time period between 4 and 24 hours, while maintaining the temperature at 45°–65° C. to yield the desired hydrolysate. Enzymatic action is then interrupted by raising the temperature to 90° C. for about 30 minutes. The liquor is screened, cooled to 55° C. and passed through a body which is supplied with approximately 75 grams of an anion-exchange resin per liter of digested mucosal tissue. The unadsorbed filtrate is stocked and concentrated and, if desired, dried.

Evaporator and spray drier combinations may be used to economically yield a dry product having appropriate functional characteristics from the hydrolyzed solution. For example, a double-effect evaporator using 500–600 BTU to remove a pound of water may be used to concentrate the product to approximately 25% solids. A spray-drier requiring 1600–1800 BTU per pound of water may be used to arrive at a product of greater than 95% solids.

In a preferred embodiment, the solution is depleted of the impurities, including heparin and certain other anionic and polyanionic impurities, by selective sorption onto an anion exchange resin. Alternatively, other conventional separation techniques such as filtration or precipitation may be utilized to separate the "impurities" from the digest solution containing the protein hydrolysate.

The sorption of the impurities onto the resin takes place in the presence of reduced initial concentrations of salt when compared to the prior art methods. In the typical case, the concentrations of salt ranges from about 0.1–450 millimolar (0.0001–0.45 molar). The sorptive material may be an ion-exchanger, or an affinity resin. The prior art method for preparation of heparin utilizes a higher concentration of salt in the digest solution, in order to minimize the sorption of anions other than heparin. The present method, on the other hand, utilizes a lower salt concentration in order to increase the sorption of other anionic and polyanionic "impurity" materials in addition to heparin, thereby removing these materials from the digest containing the protein hydrolysate. If desired, the sorbed constituents may be selectively desorbed from the resin utilizing techniques known in the art, such as elution at increasing salt concentrations.

The material not sorbed initially will be primarily protein hydrolysate and various non-polar or non-anionic constituents under the solution conditions. The heparin-depleted solution, or a mixture with various fractions subsequently eluted from the ion-exchanger, may be utilized directly, or commingled with other materials before or after concentration, drying or further processing.

A larger amount of sorptive resin is utilized in the present method than in the prior art methods. The sorption of heparin and other impurities in the prior art method occurs at a sufficiently high salt concentration in the digest solution that the sorption of materials other than heparin is minimized. The larger amount of resin in the inventive method is required in order to assure the presence of a sufficient amount of resin to sorb the greater amount of anionic and polyanionic materials that adhere to the resin at the lower salt concentrations used in the inventive method. The sorption of the anionic and polyanionic materials can further be enhanced by either adjusting the pH of the digest to conditions conducive for adsorption to the resin, or by utilizing other chromatography techniques, such as radial flow.

The particular enzyme to-be utilized in the hydrolysis is selected from among those proteolytic enzymes that are typically considered to be of a foodgrade quality. Examples of enzymes that are acceptable are proteolytic enzymes of the Subtilisin family. These enzymes are isolated from the

bacterium *Bacillus subtilis*, and are well known to those skilled in the art. Of this class, a foodgrade quality enzyme, such as Alcalase 2.4 L is preferred, although other grades or other enzymes are acceptable. Alcalase 2.4 L is commercially available from Novo-Nordisk of Bagsvaerd, Denmark.

Basic anion-exchange resins may be used in this invention for purification of the protein hydrolysate and for the isolation of anionic constituents. Such basic anion-exchange resins are commercially available, among others, under the trademarks Lewatit or Amerlite. An affinity resin, such as one containing anti-heparin, may also be used.

It is found that the protein hydrolysate obtained by the method of the present invention is low in ash, high in nitrogen and alpha amino nitrogen content, and particularly rich in glycine content.

For reference, the typical properties of the subject protein hydrolysate obtained by the method of the present invention are compared to those of other protein hydrolysates as shown below:

	Casein	Lactalbumin	Plasma	Soy	Mucosa
Total Nitrogen % d.b.	13.3	12.3	10.9	9.5	9.8
Ash % d.b.	8.2	4.0	15.0	11.5	13.8
Sodium % d.b.	3.3	0.9	6.25	2.7	4.6
Chloride % d.b.	1.1	0.56	N.A.	2.7	2.4
Amino Acid as % of Total Protein					
Alanine	3.7	4.6	4.4	3.8	7.1
Arginine	4.6	2.7	6.9	8.4	2.4
Aspartic Acid	6.7	10.1	9.2	12.8	6.9
Cystine	0.4	2.6	3.2	1.0	1.0
Glutamic Acid	18.9	19.9	12.9	21.1	16.2
Glycine	2.0	2.1	3.5	4.0	7.6
Histidine	1.9	1.6	3.6	2.3	2.5
Hydroxyproline	—	—	—	—	—
Isoleucine	5.9	5.2	2.8	4.3	5.1
Leucine	9.2	11.3	8.0	7.1	9.4
Lysine	8.4	9.2	8.8	6.1	9.0
Methionine	2.4	2.6	0.8	1.8	2.9
Phenylalanine	5.2	3.7	5.4	4.3	4.9
Proline	9.2	4.7	5.9	5.3	6.2
Serine	5.2	4.5	5.6	5.2	2.7
Threonine	5.0	4.5	6.0	4.2	5.5
Tryptophan	1.3	1.7	1.9	1.0	1.4
Tyrosine	3.0	2.7	5.1	3.0	2.8
Valine	7.0	6.3	6.0	4.3	6.4
	100.0	100.0	100.0	100.0	100.0

This invention will be further illustrated by the following examples. The examples are only provided as illustrations, and are not intended to be limiting in any manner of the scope of this invention.

EXAMPLE 1

Mucosa tissue, stabilized with approximately 25 grams of sodium metabisulfite per liter of tissue, was digested with a proteolytic enzyme of the Subtilisin family at pH 8.6 under mild heat, resulting in 1825 ml digested material having a heparin activity of 60 u/ml. 3 grams of sodium chloride per liter and 120 ml of an anion exchange resin per liter of mucosa tissue were added to the digest, and reacted for 23 hours under continuous agitation. The resin was then harvested. The filtrate had a residual heparin activity of <2.9 u/ml reflecting a 95% extraction yield, which is considered satisfactory. The filtrate had the following properties:

Oil & Grease	5200 mg/l <EPA 413.1>
Total BOD (5 day)	124,000 mg/l <SM 5210>
Total Suspended Solids	24,600 mg/l <EPA 160.2>

and had an amino acid profile as follows:

	mM Conc. (free)	Mm Conc. (total)
Aspartic Acid	58.7	109.2
Threonine	55.9	62.9
Serine	61.7	23.9
Glutamic Acid	95.0	151.6
Proline	51.5	66.8
Glycine	79.8	141.5
Alanine	103.8	111.7
Cystine	—	—
Valine	83.3	82.1
Methionine	21.3	19.0
Isoleucine	51.5	53.3
Leucine	104.2	108.5
Tyrosine	3.0	18.3
Phenylalanine	34.2	37.1
Histidine	36.6	42.5
Tryptophan	—	—
Lysine	77.8	101.3
Arginine	54.1	66.5
Ammonia	71.5	167.1

EXAMPLE 2

2125 ml of porcine mucosa tissue stabilized with 0.5% (w/v) sodium metabisulfite was digested with a proteolytic enzyme of the Subtilisin family at pH 8.4 under mild heat resulting in 2000 ml digested material with a heparin activity of 58 u/ml.

The digest was split into two equal parts:

(1) 1000 ml was processed in the same manner as Example 1 except that the amount of sodium chloride was increased to 5 grams per liter. The resin was slurried for only 18 hours. The heparin potency of the filtrate, after the isolation of resin, was 2.8 u/ml.

(2) 1000 ml was processed in an identical manner as Example 1 except that no sodium chloride was added and the resin contact was increased to 24 hours. After isolation of the resin, the heparin activity of the filtrate was assayed at 2.8 u/ml.

EXAMPLE 3

Mucosa tissue was collected and stabilized with 0.5% (w/v) calcium propionate. The pH was adjusted to 8.3 with 50% caustic soda, 1 gram of enzyme was added per liter of mucosa tissue and the slurry was held at 55° C. for 60 hours. Typical odor was observed but no spoilage had occurred. Enzyme action was stopped by heating to 90° C., holding for 15 minutes, and subsequently cooling to 55° C. 150 ml of resin per liter of slurry was added to adsorb all polyanions. After the resin-polyanion copolymer was harvested, the filtrate was analyzed. The heparin activity of the filtrate was assayed at <7 u/ml.

Solids, %	21.7
Ash, %	2.99
Kjeldahl Nitrogen, %	2.11
Total Phosphorous, %	0.27
Sodium, %	0.99
Chloride, %	0.51
Sulfite, ppm	8.2

-continued

Amino Acid Analysis	% Total	% Free
Aspartic Acid	0.80	0.40
Threonine	0.63	0.45
Serine	0.31	—
Glutamic Acid	1.87	1.23
Proline	0.71	0.56
Glycine	0.87	0.50
Alanine	0.82	0.69
Cystine	0.11	—
Valine	0.74	0.62
Methionine	0.33	0.22
Isoleucine	0.59	0.49
Leucine	1.08	0.89
Tyrosine	0.32	0.26
Phenylalanine	0.56	0.45
Histidine	0.29	0.25
Lysine	1.04	0.82
Arginine	0.28	0.08
Tryptophan	0.16	—
	11.51	7.91

EXAMPLE 4

Protein hydrolysate prepared according to Example 1 was fed under controlled conditions to newly weaned piglets. It is well known that maximum weight gain in newly weaned livestock is critical to their subsequent health and efficient growth. For this reason, proteins or other feed ingredients that enhance this early growth are of significant value.

Currently, the inclusion of spray dried animal blood plasma in diets for young pigs induces the greatest observed weight gain, and therefore sells for approximately 20 times the cost of average swine feeds. However, the supply of plasma is limited, with twice as much fed per baby pig as is recovered from a pig at slaughter. With this intrinsic imbalance between supply and demand, the price involved with the use of plasma can be expected to continue to increase even from the current level.

As an alternative to plasma, a hydrolysate (i.e., a peptone) produced from the mucosa of livestock by the inventive process was fed to newly weaned, commercial hybrid piglets. In piglet feeding experiments, hydrolysate, containing less than 15% (low ash) or approximately 30% (traditional) ash was fed as 5% of the diet in side-by-side trials against identical diets, except with plasma substituted for the hydrolysate as a bench mark for maximum performance. The results are shown in Table 1.

TABLE 1

PIGLET FEEDING TRIAL ¹		
Hydrolysate	Appetite ²	Weight Gain ³
low ash ⁴	107%	111%
Traditional ⁵	84%	83%

Notes:

¹Results are normalized against plasma performance and reported in percent.

²Appetite was measured as feed consumed by pigs of equal weight, age and genetic composition.

³Weight gain was measured as the difference in weight over the length of the trial.

⁴Differences between plasma and low ash peptone effects are not statistically significant (p < .05).

⁵Statistically significant depression in appetite and weight gain (p < .05) occurs with traditional peptone.

Protein hydrolysate is equally as effective as plasma, but at a significantly lower production cost. Furthermore, protein hydrolysate is an economic alternative to plasma. The

cost of the raw mucosa is lower than raw plasma; it is less expensive to process; and income from the sale of the crude heparin that can be isolated from its sidestream in the inventive process generates added revenue without decreasing the value of the hydrolysate. Hydrolysate produced from mucosa in the traditional heparin isolation process has substantial added salt that contributes to an unalterably high ash content that significantly detracts from its value as a feed ingredient. The inventive process therefore enables productive use to be made of not only the heparin, but also the previously discarded hydrolysate.

While this invention has been described as having a preferred embodiment, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

What is claimed is:

1. A method for the preparation of protein hydrolysate for use in providing nutrition from mammalian mucosa tissue, comprising the steps of:

providing an aqueous mixture comprising said mammalian mucosa tissue, said mammalian mucosa tissue being essentially the only tissue present in the aqueous mixture, said mucosa tissue being at least one of intestines, intestinal mucosa, intestinal skin, trachea tissue, lung tissue and liver tissue, and being derived from at least one of pigs, cattle and sheep;

hydrolyzing the mucosa tissue in said aqueous mixture with a proteolytic enzyme at a salt concentration of less than 0.1 molar, said salt being an alkali metal salt, an alkali earth metal salt, an ammonium salt of an acid, or a mixture thereof, said hydrolysis being performed at a pH of about 8.5 and at a temperature between about 45° C. and about 65° C., thereby forming a digest solution comprising said protein hydrolysate and polyanions, said polyanions comprising heparin, said salt concentration being conducive for separation of said polyanions comprising heparin from said protein hydrolysate

by adsorption of said polyanions comprising heparin with an anion exchange resin;

adding a sufficient amount of said anion exchange resin to said digest solution to adsorb said polyanions comprising heparin from said digest solution onto said anion exchange resin;

recovering said anion exchange resin and said adsorbed polyanions comprising heparin from said digest solution, a sufficient amount of said polyanions comprising heparin being adsorbed onto said resin and removed from said digest solution such that said digest solution has a residual heparin activity of less than about 2.9 u/ml; and

recovering the protein hydrolysate from the digest solution by at least one of screening and dehydration, said protein hydrolysate having the following properties on a dried basis: (a) less than 15% ash (b) between 9.5 and 11.5% total Kjeldhal nitrogen, and (c) between 5.0 and 7.0% alpha amino nitrogen.

2. The method of claim 1 wherein said aqueous mixture is hydrolyzed at a temperature of about 55° C.

3. The method of claim 1, wherein the mucosa tissue is derived from intestines.

4. The method of claim 1, wherein said protein hydrolysate is recovered from the digest solution by drying the digest solution.

5. The method of claim 1, wherein said polyanions comprising heparin are recovered from the anion exchange resin by selective elution at increasing salt concentrations.

6. A protein hydrolysate prepared by the method of claim 1.

7. The protein hydrolysate of claim 6, wherein said protein hydrolysate has the following percentages of amino acids based on percent dry basis

Glycine	4.5-6.0%
Lysine	5.5-7.0%
Methionine	0.5-2.5%
Serine	1.5-3.5%
Leucine	4.5-7.0%, and
Glutamic acid	10.0-12.5%.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,607,840
DATED : March 4, 1997
INVENTOR(S) : Cornelius L. Van Gorp et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page, Section [57], last line of Abstract, following "parenteral", delete "mutrition" and insert -- nutrition --.

Claim 1, column 10, line 18, after "total", delete "Kieldhal" and insert -- Kjeldahl --.

Claim 4, column 10, beginning on line 24 and continuing on line 25, after "protein", delete "hydrolystate" and insert -- hydrolysate --.

Claim 7, column 10, line 32, after "protein", delete "hydrolystate" and insert -- hydrolysate --.

Signed and Sealed this
Fifth Day of August, 1997



Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named

Inventor : John H..Lee et al.

Appln. No. : 09/392,243

Filed : September 9, 1999

Title : PROCESSES FOR MAKING PROTEIN
HYDROLYSATES FROM ANIMAL
PEPTONE AND FOR PRESERVING
MUCOSA

Docket No. : LL11.12-0073

Group Art Unit: 1651

Examiner: F. Prats

EXHIBIT B OF APPENDIX B IN BRIEF FOR APPELLANT

U.S. Patent No. 4,438, 100 (the Balslev patent)

United States Patent [19]

Balslev et al.

[11] 4,438,100

[45] Mar. 20, 1984

[54] STERILIZED PRESERVED, STABLE MUCINE-CONTAINING SOLUTIONS

[75] Inventors: Erik Balslev, Fredensborg; Sverre S. Hansen, Virum; Ernst L. Pedersen, Taastrup, all of Denmark

[73] Assignee: A/S Orthana Kemisk Fabrik, Kastrup, Denmark

[21] Appl. No.: 336,357

[22] PCT Filed: Apr. 27, 1981

[86] PCT No.: PCT/DK81/00043

§ 371 Date: Dec. 28, 1981

§ 102(e) Date: Dec. 28, 1981

[87] PCT Pub. No.: WO81/02977

PCT Pub. Date: Oct. 29, 1981

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[51] Int. Cl.³ A61K 35/38; A61K 33/40

[52] U.S. Cl. 424/104; 424/130

[58] Field of Search 424/104, 130

[56]

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Primary Examiner—Sam Rosen

Attorney, Agent, or Firm—Cushman, Darby & Cushman

[57]

ABSTRACT

Sterilized, preserved, stable mucine-containing solutions for use for application to sensitive human mucous membranes of the oral cavity, the nasal system, and the eye epithel contain an oxidizing bactericide, in particular hydrogen peroxide, as preservative. Even at very small hydrogen peroxide concentrations, solutions remain bactericidal over prolonged periods such as 1–2 years. Mucine used is porcine gastric mucine or bovine salivary mucine or—to adjust the polar/non-polar properties—a mixture of both.

The pronounced lubricating effect, combined with suitable viscosity, low surface tension and ability to coat and protect mucous membranes renders the solutions well suited as artificial salivas, ophthalmic solutions, and carriers for medicaments.

29 Claims, No Drawings

STERILIZED PRESERVED, STABLE MUCINE-CONTAINING SOLUTIONS

The present invention relates to sterilized, preserved, stable mucine-containing compositions and methods for their preparation.

The compositions of the present invention, which are in particular aqueous solutions (colloid solutions), utilize unique advantageous properties of mucines, especially particular kinds of mucines described below, and relate to sterilized solutions of mucine, in particular for a number of applications where the special nature of glycoproteins—together with the fact that glycoproteins constitute natural products which are extracted from animals and which, with respect to their properties, are closely related to the properties of the glycoprotein solutions secreted in the human system—has been found to be particularly beneficial. In all of the applications contemplated, special properties of mucines—including viscosity properties, surface active properties, polar/non-polar properties, lubrication properties, and ability to be effectively sterilized and preserved and even imparted bactericidal properties and to resist enzymatic degradation without to any substantial degree losing their valuable properties—render the solutions of the invention particularly well suited for direct or indirect application to sensitive human mucous membranes such as the mucous membranes of the oral cavity, the nasal system, and the eye epithel.

Thus, the solutions of the invention are, in particular, adapted for oral or nasal administration to human beings, or for closely related applications, such as for use as ophthalmic solutions. For these purposes, the solutions should be sterilized and should contain a preservative so that they will maintain sterility even when exposed to a certain contamination during storage and application.

Hence, one of the main aspects of the invention is constituted by aqueous mucine-containing compositions, in particular for application to human mucous membranes and/or for use as an ophthalmic solution, comprising a non-human mammalian mucine selected from the group consisting of buccal and gastrointestinal mucines, the composition having a viscosity of at the most 50 relative to water, as measured with an Oswald viscosimeter, said composition being sterilized and containing a preservative which is present in a physiologically tolerable concentration with respect to the application of the composition.

One of the main utilities of this aspect of the present invention is constituted by solutions for oral administration to human beings. This aspect will now be dealt with in greater detail:

It is well-known that dryness of the mouth is a frequently occurring condition. The dryness may vary from slight dryness with transitory inconvenience to a total xerostomia with severe concomitant symptoms (problems in connection with speech, mastication, swallowing, digestion and physical and psychic indisposition) and serious consequences for the buccal cavity of the patient (destruction of the teeth because of carial and/or marginal parodontite), fungal infection and a very sensitive mucous membrane with consequent difficulties in accepting dentures.

The reasons for mouth dryness may be physiological (age, menopause, postoperative conditions, dehydra-

tion), psychic (nervousness), pharmacological (anticholinergica, anti-histaminica, anti-hypertensiva, sedativa and neuroleptica) and radiotherapeutic (after irradiation of tumours on head and neck). Especially irradiation drastically reduces the normal saliva secretion.

Normally, human beings have a salivary secretion varying between 1000 and 1500 ml in the course of 24 hours. This secretion is a mixture of secretions from the submandibular, sublingual, and parotid glands. More than 98% of the mixed salivary secretion is water, 0-3% is constituted by organic substances, and about 0.25% are inorganic substances.

Among the inorganic and organic components of the natural salivary secretion, a number of substances are not normally taken together with the daily food, and therefore, deficiencies may occur in the organism if they are not supplied in another manner. The following are examples of substances, the importance of which is partially known. (The substances are listed on the basis of 1 liter of salivary secretion per day).

KSCN: 0.25 g

Mucine: 0.5-1.0 g

(mucoprotein, including bound carbohydrates) including bound hexosamines: 0.05-0.1 g

including bound sialic acid: 0.02-0.03 g

Enzymes:

including amylase: 0.4 g

and lysozyme: 0.10-0.15 g

The thiocyanate constitutes part of an antibacterial system together with lactoperoxidase (an enzyme which is also present in salivary secretion) and hydrogen peroxide which is formed in small amounts in some of the bacteria of the mouth. On oxidation with hydrogen peroxide, thiocyanate is converted into a bacteriostatically active substance (hypothiocyanite). This oxidation process is catalyzed by lactoperoxidase, but proceeds slowly even without the presence of this enzyme.

Hence, a deficiency in thiocyanate as a consequence of lack of salivary secretion is a possible reason for fungal growth, e.g., on the tongue. Such fungal growth on the tongue is a well-known problem with patients suffering from xerostomia.

The mucine in the salivary secretion possesses several important properties which are essential to the properties of the saliva. Some of the most important properties of the mucine are as follows:

A lubricating effect. The food is easily swallowed, speaking is no problem, and there is no unpleasantness from dry mucous membranes.

The mucine makes the saliva sufficiently viscous to remain on the mucous membranes, and to move slowly on the mucous membranes and act as a carrier for other substances.

The mucine has surfactant effect and, hence, reduces the surface tension of the saliva to considerably below the surface tension of water, which contributes to make the saliva "foam" and act as an emulsifier for the food intake, to enable the saliva to distribute evenly over dry mucous membranes, and to mix freely with saliva already present.

From the above explanation of the characteristics of salivary secretion and the problems which occur when the salivary secretion is deficient, it will be understood that it would be most desirable to have an artificial saliva composition for human use, to relieve the above-

mentioned inconveniences incurred by xerostomia or by a greater or lesser tendency to dryness of the mouth.

The ideal saliva composition should have physical and clinical properties which are as close to the properties of the mixed natural salivary secretion as possible. In contrast to the natural saliva in the mouth, it should be stable when stored and applied in liquid form.

As it is complicated in practice to apply the amounts corresponding to normal saliva secretion, that is, about 1-1.5 liters, of artificial saliva during a day and night in an automatic and handy way, the ideal artificial saliva should be based on intake of only 25-50 ml per day in a more concentrated form, but on the other hand combined with the intake of a relatively larger amount of water during the day, especially during meals and before sleeping.

Furthermore, for practical reasons, the ideal artificial saliva composition should be inhibitory to bacterial growth to such an extent that it can be used in refill systems, e.g., for storage during a longer period in a 1 liter bottle from which portions of the composition are withdrawn under non-sterile conditions at intervals and are transferred to a more handy container, e.g., a 25 ml vial, such as a plastic container, which may easily be kept in a pocket or small bag, and from which suitable portions can be taken by suctioning or sucking.

Besides the traditional household remedies such as gruel, glycerine, etc., the most used known artificial saliva compositions are based on carboxymethylcellulose as the medium which imparts, to the saliva composition, its lubricating effect and the necessary viscosity. Such a composition is described by J. Matzker in *Z. Laryng. Rhinol.* 51, 422-428 (1972) and contains 10 g of carboxymethylcellulose per liter, 30 g of sorbitol per liter, and small amounts of dissolved salts (potassium chloride, sodium chloride, magnesium chloride, calcium chloride, potassium hydrogen phosphate, and potassium thiocyanate).

The composition of this known artificial saliva is close to the composition of natural unstimulated saliva, apart from the essential components constituted by carboxymethylcellulose and sorbitol which have been added to impart lubricating and viscous properties to the saliva.

This known artificial saliva, and similar compositions, are widely used. They are nearly all based on sodium carboxymethylcellulose (in the following termed "carboxymethylcellulose" for brevity) and sorbitol and are preserved with methyl-p-hydroxybenzoate or other bactericidally and/or fungicidally active synthetic organic compounds.

Unfortunately, these known artificial saliva compositions suffer from the disadvantage that patients using them complain about sticky accumulations at particular sites in the mouth. Under these layers, irritation of the mucosa has been observed. Many patients complain of unpleasant taste and of the fact that the lubricating effect in the mouth is of relative short duration.

One reason for these disadvantages may be that the essential component of the composition, carboxymethylcellulose, which comprises a different molecular structure from the molecules of the mucoproteins occurring in natural saliva, results in a high viscosity of the artificial saliva and a relatively high surface tension which by no means approaches the low surface tension of the natural saliva. Thus it has been found that the surface tension of compositions containing 1% by weight of carboxymethylcellulose together with 3% by

weight of sorbitol is in the range of 60-65 dyn.cm whereas the surface tension of natural saliva is in the range of 48-53 dyn.cm.

Another reason for the disadvantages of the known artificial saliva compositions may be that the preservatives used therein differ very much from substances normally occurring in the saliva and hence may irritate the oral mucous membranes, in particular when their concentration increases with evaporation of the water of the composition. Also, the preservatives used in known artificial saliva compositions, even the above-mentioned methyl p-hydroxybenzoate which is most widely used for this purpose, has an unpleasant taste in high concentrations.

In 1974 it was shown that an artificial saliva containing 1% of mucine prepared from bovine salivary glands is preferred by patients suffering from xerostomia, over saliva compositions based on carboxymethylcellulose, as the mucine-containing composition had a better taste and remained in the mouth for a longer period, (E. J. 's-Gravenmade et al., *Int. J. Oral. Surg.* 1974:3, 435-439).

The artificial saliva compositions used for the experiments were prepared by dissolving 100 mg of lyophilized bovine salivary mucine extract in 10 ml of water. None of the solutions were used for more than 2 days at room temperature. Although the bacterial count for the artificial saliva composition has been low immediately after its preparation, there is no doubt that a longer term storage thereof at room temperature or in a refrigerator would result in a considerable increase in the bacterial count. Furthermore, it was not easy to obtain a sufficiently homogeneous solution of the mucine, as an ordinary stirring into water by the user is relatively time-consuming and yields a varying result. A non-homogeneous solution, when taken, can result in varying deposits of the mucine on the mucous membrane, which is inexpedient.

The present invention provides an artificial saliva composition, and, in a broader sense, a composition for oral administration to human beings, which is not associated with any of the above-mentioned drawbacks, and which conforms to the characteristics of an ideal artificial saliva composition.

The composition of the invention containing a non-human mammalian mucine selected from the group consisting of buccal and gastrointestinal mucines has a low bacterial count obtained by sterilization and by means of a preservative incorporated in the composition. The composition of the invention is preferably substantially free from any mucine-decomposing enzymatic activity.

In the present specification and claims, the term "preservative" is intended to designate a substance showing antimicrobial properties, in particular bactericidal properties and preferably also antifungal properties. As will appear from the following description, oxidizing bactericides, including peroxides and in particular hydrogen peroxide, are preferred preservatives for the purpose of the present invention.

As will be understood, the composition, when ready for use, will contain the mucine in aqueous solution (or, expressed more correctly, in aqueous colloid solution), but it is within the scope of the invention to supply the composition in the form of a dry formulation, e.g. a powder or granulate, for reconstitution before use.

Due to the low bacterial count (usually as low as at the most 10 bacteria per gram of the composition), the

composition will, in practice, be free from any bacterial degradation or contamination. Due to the freedom from any mucine-decomposing enzymatic activity, the composition will be substantially free from any enzymatic degradation of the mucine.

In the present context, the term "buccal and gastrointestinal mucines" is intended to designate any mucine which is present in the oral cavity or in the gastrointestinal system. Typical examples are mucines from salivary glands and gastric mucines.

As stated above, a low bacterial count, typically of at the most 10 per gram, in the composition of the invention is obtained by means of a preservative. The preservative (or combinations of preservatives) having bactericidal and, preferably, also fungicidal properties may be present in the final composition, or may be included in the preparation of the composition in such a way that it is substantially no longer present in the final composition, or it may be both included in the preparation of the composition and added in such a way that it is present in the final composition, such as will be understood from the more detailed explanation to follow.

When medicaments or other agents for human oral administration are sterilized, this is normally performed, e.g., by an autoclave treatment or by filtration through a sterile filter. If it were attempted to sterilize mucine-containing compositions by autoclave treatment, the viscosity of the mucine would degrade drastically, which in practice would make the mucine less applicable for the purpose of the invention. Furthermore, a filtration of the mucine-containing composition through a sterilizing filter is difficult. More importantly, however, none of these methods of sterilization contribute to any preservation of the product.

Therefore, the obtaining of sterility by means of a preservative in accordance with the present invention is a very important feature characterizing the process and the product of the invention.

As stated above, the composition of the invention contains a preservative, in order to secure that it will remain free of bacterial growth even if it is not stored and handled under sterile conditions. On the other hand, if the bacterial count of an artificial saliva composition of the mucine-containing type according to the present invention has been lowered to at the most 10 per gram by treatment with a preservative during the preparation of the composition, and the composition is kept under sterile conditions, it might not be necessary that the composition still contains any preservative, but it is, nevertheless, always preferred according to the present invention that the composition contains a preservative.

The composition of the invention has preferably been treated and/or admixed with preservative to such an extent that its bacterial count remains substantially constant for a period of at least one year when the composition is kept in a closed container at room temperature, and more preferably, to such an extent that the bacterial count of the composition remains substantially constant when the composition is kept at 4° C. for a period of two months with occasional withdrawal of a portion of the composition, typically daily withdrawal of a portion of the composition.

Under the same conditions and during the same periods as stated above in connection with the bacterial count, the viscosity of the composition, when it is an aqueous solution, should preferably be stable to such an extent that it does not decrease to below 2, relative to water. This is obtained when any mucine-decomposing

enzymatic activity has been substantially removed from the composition, and any preservative or preservatives present, and the concentration thereof, are suitably selected.

According to the invention, it has been found that an ideal preservative for the obtainment of the above-mentioned critical stability properties is an oxidizing bactericide. Examples of known oxidizing bactericides are ozone and peroxides, in particular hydrogen peroxide. Hydrogen peroxide serves both as a means to eliminate mucine-decomposing enzymatic activity, and as an efficient microbiocidal agent. According to the invention, it has been found that in the combination with the mucine, hydrogen peroxide, even in very low concentration, is surprisingly effective as a bactericide. Hydrogen peroxide may be used for treating the mucine material used in the composition of the invention prior to incorporating the mucine material into the composition, or for addition to the composition, or both. When hydrogen peroxide is present in the composition, it will not only serve as a preservative to keep the composition free from microbial growth when the composition is exposed to bacterial and fungal contamination, but will also impart a most desirable "freshness" to the composition. Furthermore, hydrogen peroxide will contribute to the natural bacterial and fungal balance of the oral cavity, since hydrogen peroxide plays an important role in this regard under the normal conditions prevailing in natural saliva secretion conditions. In this regard, and in other regards as will be explained below, hydrogen peroxide is preferred over other microbiocidal preservatives which can be administered to the oral cavity of human beings and which could therefore also be used for the purpose of the present invention but which have an unpleasant taste in the necessary concentrations thereof, such as chlorohexidine and methyl p-oxybenzoate.

According to the invention, the oxidizing bactericide is preferably present in the composition in a concentration of about 0.01-70 millimol per liter, such as 0.1-70 millimol per liter, in particular 0.05-20 millimol per liter, such as 0.5-10 millimol per liter.

When the oxidizing bactericide is hydrogen peroxide, a typical initial concentration thereof is about 10 millimol per liter.

The oxidizing bactericides, in particular exemplified by ozone and hydrogen peroxide, are active in extremely small concentrations. Thus, remarkable antibacterial and anti-fungus effects have been noted in the compositions of the present invention even long time after the concentration of oxidizing bactericide has decreased, during storage, to nearly zero.

Thus, e.g., when 600 ppm of hydrogen peroxide is added to a mucine-containing solution in the sterilization treatment, the hydrogen peroxide concentration will, after a few weeks, drop to about 300 ppm, after half a year to 50-100 ppm, and after one year, the concentration will be only slightly above zero. With ozone, the concentration will decrease more rapidly, from, e.g., 1 mg/liter to close to zero in a few hours.

Thus, it is characteristic to the sterilization and preservation with these oxidizing bactericides that the relatively high initial concentration thereof used in the sterilization process decreases rapidly during the initial short period whereafter a physiologically tolerable, but still bactericidally effective concentration is retained during the following storage and application period.

In a particular embodiment, the composition of the invention also contains other constituents which may serve to substitute saliva constituents, such as ion species found in human saliva, typically one or several ions selected from the group consisting of sodium, potassium, chloride, calcium, phosphate, magnesium, bicarbonate, and thiocyanate.

According to a preferred feature of the invention, the composition contains a thiocyanate, typically in a concentration of from 0.25 mM to 6 mM, in particular from 0.5 mM to 2 mM. Thiocyanates have a certain antimicrobial activity which is, of course, a desired property in the composition of the invention, but more important, thiocyanate is a constituent of human natural saliva and, as explained above, constitutes part of an antibacterial system comprising thiocyanate, hydrogen peroxide, and lactoperoxidase. When hydrogen peroxide and thiocyanate are present in the composition of the invention, such as is preferred, two components of this system are supplied by the composition. The third component of the system, lactoperoxidase, is present in any salivary secretion with which the patient may be able to contribute, or can be supplied from, e.g., milk which the patient drinks. Another interesting possibility is to include, in the composition of the invention, a system which will generate hydrogen peroxide in situ in the composition for balanced co-operation with the thiocyanate, e.g., a system comprising enzymes which, in the mouth, together with polysaccharides from the food generate hydrogen peroxide, such as a combination of amyloglucosidase and glucosyl oxidase.

The composition of the invention may also contain fluoride ions, e.g. incorporated as sodium fluoride, in order to obtain a rehardening effect on dental enamel. When sodium fluoride is incorporated in the composition, it is normally incorporated in an amount of, e.g., 0.5-5 ppm, preferably 2 ppm.

The artificial saliva composition of the invention is preferably made with such a viscosity that the mucine thereof will remain as a protective coating on the surfaces of the mouth for a sufficiently long period. For practical reasons, it is desirable that the necessary doses of the artificial saliva are relatively small so that the patient can easily carry a small container containing the necessary volume for a period of e.g., one day and night, typically a volume of 25-50 ml, which means that suitable doses should be about 1-2 ml. When supplied from such small volume doses, the mucine of the composition should be capable of substantially substituting for the deficient saliva excretion. A suitable viscosity to obtain this is a viscosity of between 2 and 30 relative to water, as measured with an Oswald viscosimeter, preferably a viscosity between 4 and 10, in particular between 5 and 8. The suitable viscosity of the solution may be obtained by proper selection of the mucine, the pretreatment of the mucine, and the concentration of the mucine. It is within the scope of the invention to include, in the composition, other viscosity-imparting constituents than mucine. For example, one possibility that could be of interest would be to combine the mucine with a carbohydrate which is viscous in aqueous solution, such as carboxymethylcellulose.

According to the invention, it has surprisingly been found that a most desirable mucine for use in the composition is gastric mucine. In spite of its gastric origin, gastric mucine has been found, in practice, to function excellently as the mucine component of artificial saliva compositions. Porcine and bovine gastric mucine may

be obtained on industrial scale at reasonable cost, and hence provide realistic mucine sources for artificial saliva compositions. Of course, gastric mucine could be combined with carboxymethylcellulose and/or with other mucines such as bovine salivary mucine. According to a particular aspect of the invention, compositions containing a combination of gastric mucine and bovine salivary mucine offer important advantages as artificial saliva compositions, such as is explained in greater detail below. In the following, porcine gastric mucine, which is an excellent mucine for the purpose of the present invention, will be dealt with in greater detail, but it will be understood that also other mammalian gastric mucines, in particular bovine gastric mucine, are valuable mucines for the purpose of the invention.

When porcine gastric mucine is used as the mucine component of the composition, it should be included in an amount corresponding to 0.2-6% by weight, typically 0.5-6% by weight, calculated on the mucine solution. Normally, the preferred concentration of the porcine gastric mucine is 1-4% by weight, calculated on the solution, but a slightly higher concentration, such as 2-5% by weight, may also be of particular interest.

Porcine gastric mucine is obtainable as a by-product in the production of pepsin from hog stomachs. When porcine gastric mucine is to be used for the purpose of the present invention, it is suitably prepared in a more pure form than the one normally produced. Such additional purification may be obtained by several alcohol precipitations, such as 2-3 precipitations with 60% ethanol. During the precipitations, and during the manipulation of the mucine, the use of gentle conditions will result in minimizing of viscosity-decreasing degradation. The purification is typically performed to such an extent that the mucine is substantially free of any peptone content. Thereafter, the resulting mucine is suitably treated with a preservative and dried, e.g. by spray drying. When the drying is performed by spray-drying, shelf-drying, or freeze-drying, it is preferred that the preservative be a low molecular weight volatile preservative such as hydrogen peroxide, which is suitably added to the mucine-containing solution to a concentration corresponding to about 0.01-0.2, suitably about 0.02-0.06, percent by weight. After the addition of the hydrogen peroxide, and prior to the spray-drying, the solution is suitably allowed to stand for a period between an hour and a few hours, typically about two hours, at room temperature. It has been found that this treatment will not only result in a material which is free of bacteria (has a bacterial count of at the most 10 per gram), but will also serve to remove any reminiscent bad taste from traces of peptones and fat. The spray-drying should be performed under conditions which are non-severe, a typical example of a preferred air inlet temperature being in the range of 150°-240° C., typically around 200° C., and the outlet temperature being in the range of 90°-180° C., typically about 150° C.

The above-mentioned conditions with respect to precipitation, addition of hydrogen peroxide and drying, are applicable also to other types of mammalian buccal and gastrointestinal mucines, including bovine gastric mucine and bovine and porcine salivary mucines.

Bovine salivary mucine may be obtained, e.g., as described by E. J. 's-Gravenmade et al., *Int. J. Oral Surg.*, 1974:3, 435-439.

When the drying is performed according to the above methods, the mucine-containing solution is preferably sterilized prior to drying, e.g. by adding a preservative.

The preferred preservative is hydrogen peroxide added in a concentration of 0.02-0.06 percent by weight.

The dried mucine preparation, in the form of a powder or a granulate having a bacterial count of less than 10 per gram, constitutes, in itself, a valuable composition of the invention. This composition can be shipped and stored under conditions which will retain its low bacterial count, and can then be reconstituted with water by the end user. Any added constituents as discussed above and in the following detailed description concerning the liquid composition can be included before the drying stage. Thus, e.g., a solid peroxide, e.g. in powder form, may be added to ensure a preserved and stable solution when the dried mucine preparation is dissolved in water.

The preferred artificial saliva composition of the invention, however, is a liquid composition of the concentration in which it is to be applied by the end user. For the preparation of a composition of this type containing one type of mucine, e.g., porcine gastric mucine, or a combination of two types of mucine, the dried mucine preparation is dissolved in preferably deionized water to a concentration corresponding to the desired viscosity of the product. The exact concentration desirable for a particular mucine preparation is easily found by preliminary experiments. When the mucine is porcine gastric mucine, the concentration will normally be in the range of 1-5% as mentioned above, but depending upon whether also other viscosity-building constituents such as carboxymethylcellulose are included, the range may be somewhat broader, e.g. 0.5-5%. To the solution, any other constituents to be included are added under gentle stirring to obtain complete solution. When a preservative is to be added to the liquid composition, this is preferably hydrogen peroxide which is added in a concentration of typically from about 1 millimol per liter to about 70 millimol per liter, preferably about 10-20 millimol per liter.

It has been found that a decrease in viscosity will take place during the sterilization treatment. A decrease in viscosity will also take place during the later storage and application period. At a concentration of 4% of mucine, the viscosity will typically be in the range of 10-4 times that of water, as measured with an Oswald viscosimeter, the viscosity reducing towards the lower bound of this range during the final part of the storage period of 1-2 years.

The surface tension of the artificial saliva composition of the invention is preferably in the range of 40-60 dyn.cm.

A composition containing porcine gastric mucine in a concentration of 3-4% by weight together with ions of the types listed below has been found to have a surface tension of 50-52 dyn.cm, which is close to the surface tension of natural saliva. Furthermore, it has been found that the relationship between the polar and non-polar properties of a composition containing porcine gastric mucine may be adjusted to a less polar value by adding bovine salivary mucine which, at the same time, reduces the surface tension of the composition. Thus, a composition containing 2% of bovine salivary mucine has a surface tension of 44 dyn.cm and shows surprising non-polar properties.

A composition which contains porcine gastric mucine and bovine salivary mucine in a proportion of 99:1 will show properties very close to natural saliva with respect to surface tension and the relationship between polar and non-polar properties. It has been found that a

solution containing 4% of porcine gastric mucine and 0.1% of bovine salivary mucine has a proportion between polar and non-polar components corresponding to about equally pronounced polar and non-polar properties, which has also been found to be the balance prevailing under natural conditions in the mucosa.

In accordance with the above explanation, one aspect of the invention comprises a composition containing a combination of porcine gastric mucine and bovine salivary mucine. Preferably, such composition contains a preservative and optionally other constituents in accordance with the principles discussed above. The composition may be an aqueous solution or it may, like the peroxide-containing compositions of the present invention, be a dry composition for reconstitution into an aqueous solution.

The compositions of the invention which contain a combination of porcine gastric mucine and bovine salivary mucine may vary within wide ranges with respect to the ratio between the two types of mucine. Thus, the weight ratio between porcine gastric mucine and bovine salivary mucine in the composition may be from 1:1000 to 1000:1, depending on the desired properties of the composition with respect to surface tension, etc, in particular between 30:1 and 200:1, and preferably between 100:5 and 100:0.5 when the composition is an artificial saliva composition, although also the range between 15:3 and 15:1 is interesting for this purpose.

As examples of suitable liquid compositions of the invention may be mentioned the compositions illustrated in the below working example, and the following examples (all percentages being by weight): (1) An aqueous solution containing 1.0% of porcine gastric mucine, 0.2% of carboxymethylcellulose, and 0.02% of hydrogen peroxide, (2) an aqueous solution containing 0.5% of bovine salivary mucine, 1.0% of porcine gastric mucine, 0.04% of hydrogen peroxide, and 0.02% of KSCN, (3) an aqueous solution containing 2.0% of bovine gastric mucine, 0.01% of KCl, 0.08% of NaCl, 0.005% of $MgCl_2 \cdot 6H_2O$, 0.02% of $CaCl_2 \cdot 6H_2O$, 0.02% of KSCN, 0.035% of K_2HPO_4 , and 0.03% of H_2O_2 , (4) an aqueous solution containing 0.3% of bovine salivary mucine, 3.0% of porcine gastric mucine, 0.02% of hydrogen peroxide, 0.08% of NaCl, 0.005% of $MgCl_2 \cdot 6H_2O$, 0.02% of $CaCl_2 \cdot 6H_2O$, 0.02% of KSCN, 0.035% of K_2HPO_4 , 2.0% of glycerine, 2 ppm NaF, (5) an aqueous solution corresponding to (4), but containing 0.1% of bovine salivary mucine and 4.0% of porcine gastric mucine, and (6) an aqueous solution corresponding to (4), but without any added bovine salivary mucine and optionally without NaF.

In the final stage, the solution is filtered to remove any particles remaining, e.g. through a filter having a pore size corresponding to Zeiss K5. The resulting solution is clear and "fresh" with a bacterial count below 10 and can be stored for more than 12 months at 4° C. in a container from which portions were withdrawn occasionally, such as once a day during a period of 2 months.

Examples of other constituents added to the composition are, apart from viscosity-building agents such as carboxymethylcellulose, enzymes of types which are present in human saliva, such as amylase, lysozyme, lactoperoxidase, etc. The enzymes and the hydrogen peroxide should be used in concentrations which are balanced in relation to each other.

EXAMPLE 1

From the preparation of pepsin described in U.S. Pat. No. 2,305,714, the supernatant liquid from which pepsin may be precipitated with alcohol is subjected to a precipitation by addition of 60% ethanol. To obtain a higher purity, the mucine precipitated (which corresponds with the NNR specifications (NNR=New and Non-official Remedies, ed. 1953, page 195)) is redissolved to a 10% solution in tap water at a temperature of 20°-25° C. by careful stirring with a slowly rotating blade stirrer. The dissolution and precipitation procedure (60% ethanol) is repeated until all peptones have been removed from the mucine (normally 3 times). Due to the gentle treatment, the resulting mucine is a mucine having a relatively high viscosity; when triturated with water, it yields a viscous, opalescent coloured solution. In dry state, the mucine is an almost white powder which is nearly odourless. The powder typically has the following data:

Mucine content: 73-94%
 Ash (500° C.): max. 6.5%
 Loss on drying (at 105° C.): max. 6.0%
 Solubility: completely soluble in water
 pH (2% solution): 3.7-6.5
 Relative viscosity (2% sol. compared with water): 3.5-15
 Total nitrogen: 6-9.9%
 Nitrogen (alcohol extract): 6-9%
 Reducing material (equivalent of dextrose): 15-35%
 Heavy metals: less than 30 ppm.

This material is subjected to treatment with preservative (H₂O₂) in the following manner:

The mucine is dissolved as a 10% solution by addition of water at a temperature of about 20°-25° C. Per thousand liters of the solution, 1 liter of 30% H₂O₂ is added; and thereafter, the solution is allowed to stand for 2 hours to destroy bacterial and enzymatic activity and to remove any unpleasant taste from traces of peptones and fat.

Thereafter, the solution is spray-dried using an inlet air temperature of 220° C. and an outlet temperature of 160° C. The resulting spray-dried product has a bacterial count of less than 10 per g. An alternative drying procedure which is also suitable is freeze-drying or shelf drying.

The resulting dried product is subjected to a viscosity assay by preparing solutions containing 2, 3, 4, etc. percent by weight and measuring the viscosity of the solutions, using an Oswald viscosimeter. Normally, a 4% by weight solution will have an initial Oswald viscosity between 10 and 20 depending on the mucine used. In the present specific example, a 4% solution in deionized water shows a relative Oswald viscosity between 15 and 20.

To the solution of the mucine in deionized water, the following ingredients are added with gentle stirring.

Ingredients added per liter:

Mucine (prepared as described above): 45 g

KCl: 1.2 g

NaCl: 0.85 g

MgCl₂·6H₂O: 0.05 g

CaCl₂·6H₂O: 0.15 g

KSCN: 0.10 g

K₂HPO₄: 0.35 g

Flavouring agent: q.s.

To this composition may, if desired, be added NaF 2 ppm and/or sorbic acid 0.50 g.

The resulting solution might be used per se as a saliva substitute, but in order to obtain long-term stability even under conditions where the composition may occasionally be exposed to the surroundings, such as when a small portion thereof is withdrawn, a preservative is added, typically a 30% aqueous hydrogen peroxide solution to a concentration of 0.6 g per liter. Finally, the resulting solution is filtered through a K5 Zeiss filter and is packed in 1 or ½ liter bottles with screw caps having a small orifice for withdrawal of portions of the composition into multidose tubes.

Alternatively, the composition is filled directly into multidose tubes of 25 to 50 ml corresponding to 1 day's consumption, or it may be filled into aerosol containers of, e.g., 30 or 75 ml size.

As an other alternative, the solution of the invention may be incorporated as the liquid into a gum emulsified liquid package of the kind disclosed in U.S. Pat. No. 4,233,288, which package may contain up to 50% of the composition. The incorporation into the package is performed in analogy with the disclosure of the said U.S. patent. Also other emulsions may be formulated in which the solution of the invention is incorporated as one of the phases.

A composition prepared as described in Example 1, but additionally containing 30 g/liter sorbitol added together with the other constituents, was used for pilot study in 20 patients with severe xerostomia. The results were very encouraging, as all patients except one reported a much better sensation in the oral cavity, a feeling of relief and easiness during mastication and swallowing, and cessation of obstipation when using the composition.

Objectively, candidosis in 5 patients out of 7 with oral and pharyngeal candidoses after 1-2 weeks of irrigation with the artificial saliva. The candidosis reappeared when the agent was discontinued.

EXAMPLE 2

In the composition of Example 1, the 4.5% of porcine gastric mucine were replaced with a combination of 3% porcine gastric mucine and 0.3% bovine salivary mucine in order to improve surface tension and non-polar properties. The mucines of this composition were analyzed (PGM=porcine gastric mucine; BSM=bovine salivary mucine):

	PGM	BSM
Protein	43.9%	57.6%
Sialic acid	1.2%	6.4%
Hexosamin	16.0%	6.2%
Hexose	19.9%	2.7%

It appears from the above analyses that the combination of the two mucines may not only be of importance from a surface tension point of view, but also because of the fact that the ratio between the contents of the essential components sialic acid and hexosamine can be combined to a particular desired value by suitable combination of the two types of mucine. Instead of being supplied as aqueous solutions, the above-exemplified compositions could be supplied in dry form, with the same relative proportions between the components.

While the preceding discussion has primarily dealt with artificial saliva compositions, it is also within the

scope of the present invention to provide compositions comprising a non-human mammalian buccal or gastrointestinal mucine for oral administration for other purposes, such as for relieving throat irritation or for acting as a carrier for medicaments to be supplied on mucous membranes in the mouth, including on the tongue, or in the throat. For such uses, the compositions will often be formulated to a somewhat higher viscosity than the viscosities which are preferred when the compositions are used as saliva substitutes. The uses of the compositions of the invention for oral administration of medicaments is especially interesting in connection with medicaments which, by the mucine content of the composition, are carried to, and retained on, the mucous membranes (or even to some extent penetrating into mucous membranes). When the mucine-containing compositions of the invention, possibly with somewhat higher viscosity than discussed above, are used for this purpose, the inherent medicament carrier-capabilities, and the mucines' capability of rendering the medicaments bio-available at mucous membranes, are utilized. Also the low surface tension of the mucines contribute to enhance the bio-availability of medicaments incorporated in such compositions. Apart from liquid compositions, also solid compositions which dissolve on sucking in the mouth, are contemplated mucine-containing compositions of the invention for oral use, for example, compositions for relieving irritations in the throat, or compositions where the mucine is associated with medicaments for treating the mouth or the throat. An example of such a medicament for oral administration is an antitussive, e.g., a composition containing 4% of porcine gastric mucine, 0.0007% of ephedrine, 0.0007% of ammonium chloride, and 0.02% of hydrogen peroxide, or a corresponding composition containing morphine.

Another main aspect of the application of the compositions of the invention is as compositions for nasal administration to human beings:

Many individuals suffer from dryness of the nose. By applying water to the nasal mucosa, only a brief moistening and relief is obtained. According to the present invention, sterilized and preservative-containing compositions comprising a non-human mammalian mucine selected from the group consisting of buccal and gastrointestinal mucines are used as nasal compositions for giving a relief and moistening of longer duration.

Compositions of the invention for use as nasal solutions are suitably composed in substantially the same manner as the oral compositions discussed above, the viscosity of the final composition when packed ready for use typically being of the order of 1-5, relative to water. The capability of the solution to properly moisten the nasal mucosa increases with decreasing surface tension of the composition, and hence, the low inherent surface tension of solutions containing mucines is of special value for this application. Another valuable property of the composition for this particular purpose is its capability to bind water to avoid dripping noses, e.g. with patients suffering from nasal catharr.

As examples of compositions of the invention for nasal application may be mentioned an aqueous solution containing 1% of porcine gastric mucine, 0.01% of hydrogen peroxide, 1% of glycerine, and flavouring agent q.s., e.g., mint oil. Instead of porcine gastric mucine, bovine salivary mucine may be used, e.g., in an amount of 0.3%, or a combination of porcine gastric mucine and bovine salivary mucine may be used, e.g.,

0.5% of porcine gastric mucine and 0.2% of bovine salivary mucine.

The compositions of the invention for nasal application are prepared in the same manner as described above for the compositions for oral application, and again, hydrogen peroxide is the preferred preservative and is preferably used in the same concentrations as discussed above.

A further aspect of the application of the composition of the invention is as ophthalmic solution.

Ophthalmic solutions, that is solutions for the cleaning and care of contact lenses, are divided into two main types, that is, wetting solutions, and soaking and cleaning solutions. Wetting solutions are first discussed.

Contact lenses, in particular hard contact lenses, are hydrophobic (water repellent) and should be wetted before they are inserted into the eye. By the wetting, the following beneficial effects are obtained:

- discomfort during insertion is minimized;
 - the optical performance is improved;
 - lens contamination during the insertion is prevented.
- Wetting solutions should have the following properties:

- they should show adequate wetting effect and such a viscosity that the solution adheres to the lens during insertion of the lens;
- they should be sterile and self-sterilizing.

Conventional ophthalmic wetting solutions contain methyl cellulose as viscosity-building agent and polyvinyl alcohol as wetting agent in an isotonic solution containing sodium and potassium chloride. The solution is normally preserved with benzalkonium chloride.

According to this aspect of the present invention, a composition according to the invention, that is, an aqueous sterilized and preservative-containing solution of a non-human mammalian mucine selected from the group consisting of buccal and gastrointestinal mucines, is adapted for use as an ophthalmic wetting solution. An example of such a composition of the invention is a solution comprising an isotonic solution of a mucine with hydrogen peroxide incorporated as preservative. According to this aspect of the invention, the unique surface activity and viscosity properties of these mucines, combined with their other beneficial properties as discussed above, render them unique constituents of ophthalmic solutions meeting the above-mentioned requirements.

Depending upon the hydrophobic properties of the contact lenses to be treated with the solution, the mucine should be, e.g., a porcine gastric mucine or a bovine salivary mucine, or a combination thereof. Solutions of bovine salivary mucine which show more non-polar properties than solutions of gastric mucines should be selected for more hydrophobic lens types. In accordance with what has been described above, the mucine in the composition also functions as a viscosity-imparting agent in the ophthalmic solutions of the present invention.

As explained above, hydrogen peroxide, when used as both the sterilizing principle and as the preservative present in the final solution, will decrease in concentration with time. As a hydrogen peroxide concentration of 50 ppm and less is presumed to be a tolerable, physiologically acceptable concentration of hydrogen peroxide in ophthalmic solutions which come into direct contact with the eye, the composition of the invention, when used for this purpose, may be sterilized by adding hydrogen peroxide to an initial concentration of about

100 ppm, which concentration will, already after about one week, have decreased to about 50 ppm and less and must be presumed to be in the range of 50 to 5 ppm at least one year later, still with the surprising preserving effect yielding the sterility which is characteristic of compositions of the invention containing hydrogen peroxide as preservative.

Ophthalmic soaking and cleaning solutions will now be discussed:

On withdrawal from the eye, a contact lens should be stored in a soaking solution which exerts the following functions:

It prevents any ocular secretion remaining on the lens from solidifying or even hardening.

It sterilizes the lens and maintains its sterility.

It maintains the hydrated equilibrium of the lens while it is not being worn.

Like the wetting solution, a typical soaking solution contains an antibacterial agent, but often in a higher concentration than in the wetting solution. The typical soaking solution also usually contains a solubilizing agent to loosen any residues attaching to the lens, and distilled water. Normally, the lens is rinsed in cold water after being withdrawn from the soaking solution.

According to the present aspect of the invention, the above-described type of sterilized, preservative-containing mucine solution which constitutes a suitable ophthalmic wetting solution for a given type of contact lens, also constitutes a suitable soaking solution for the same type of contact lens, due to the unique sterile and sterilizing properties of the composition, and because the mucine in itself has properties which permits it to function as a solubilizing and cleaning agent.

Thus, according to this aspect of the invention, the system comprising mucine and a concentration of hydrogen peroxide which is sufficiently low to allow the introduction of the composition into contact with the eye epithel, while still being sufficiently high to warrant the sterilizing properties of the system, opens the possibility of establishing a combined ophthalmic solution which combines the properties and functions of both the wetting solution type and the soaking and cleaning type of ophthalmic solution.

Due to their unique properties, compositions of this type and with viscosities, isotonic properties, and surface tension properties suitably adapted, may also be used as solutions for application on the eye for other purposes than in connection with contact lenses.

As will be understood on the background of the above explanation and as appears from the claims, separate novel aspects of the present invention comprise a sterilized composition comprising a non-human mammalian mucine selected from the group consisting of buccal and gastro-intestinal mucines and containing an oxidizing bactericide, especially a peroxide, in particular hydrogen peroxide, as a preservative. The said composition will preferably show the features discussed above and may be an aqueous solution as discussed above, or it may be a dry composition for reconstitution. Another novel aspect of the invention is a composition comprising a combination of porcine gastric mucine and bovine salivary mucine. A third aspect of the invention comprises a method for sterilizing mucine-containing aqueous compositions by adding an oxidizing bactericide, in particular a peroxide such as hydrogen peroxide, thereto. In this aspect, the hydrogen peroxide is suitably added to a concentration of about 100-300 ppm, such as a concentration of about 250 ppm.

From the above discussion, it will be understood that the compositions of the invention, due to the unique properties of the mucines and combinations thereof for the particular purposes stated or for other purposes where a physiologically tolerable surfactant is desirable, constitute very valuable products, especially when they are sterilized and preserved by means of hydrogen peroxide which, as explained above, shows a surprisingly beneficial combination of properties in that it is capable of effectively sterilizing and preserving the compositions when used in such low concentrations that it does not in any way interfere with the use of the compositions for application on even very sensitive human mucous membranes.

French Patent Specification No. 3,554 M discloses mucine-containing compositions for treatment of human mucous membranes and discloses examples of such compositions for, e.g., treatment of infections in nose or mouth. The disclosure of this French specification does not teach how one could sterilize and preserve—in a manner which would be physiologically tolerable with respect to the application of the compositions of the present invention—a mucine-containing solution so as to ensure that the solution will remain stable and bactericidal under the conditions which are fulfilled by the compositions of the present invention.

We claim:

1. An aqueous mucine-containing composition, in particular for application to human mucous membranes and/or for use as an ophthalmic solution, comprising a non-human mammalian mucine selected from the group consisting of buccal and gastrointestinal mucines, the composition having a viscosity of at the most 50 relative to water, as measured with an Oswald viscosimeter, said composition being sterilized and containing an oxidizing bactericide preservative which is present in a physiologically tolerable concentration with respect to the application of the composition.

2. A composition as claimed in claim 1 which is substantially free from any mucine-decomposing enzymatic activity.

3. A composition as claimed in claim 1 or 2, in which the bacterial count of the composition remains substantially constant for a period of at least one year when the composition is kept in a closed container at room temperature.

4. A composition as claimed in claim 3 in which the bacterial count of the composition remains substantially constant when the composition is kept at 4° C. in a container from which a portion of the solution is withdrawn occasionally during a period of two months.

5. A composition as claimed in claim 1 in which the oxidizing bactericide preservative is a peroxide.

6. A composition as claimed in claim 1 in which the oxidizing bactericide preservative is present in a concentration of about 0.01-70 millimol per liter.

7. A composition as claimed in claim 6 wherein the oxidizing bactericide preservative is hydrogen peroxide and is present in an initial concentration of about 10 millimol per liter.

8. A composition as claimed claim 1 or 2 in which the mucine is porcine gastric mucine and/or bovine salivary mucine.

9. A composition as claimed in claim 8 in which the mucine is a combination of porcine gastric mucine and bovine salivary mucine.

10. A composition as claimed in claim 9 wherein the weight ratio between porcine gastric mucine and bo-

vine salivary mucine in the composition is from 1:1000 to 1000:1.

11. A composition as claimed in claim 10 wherein the weight ratio between porcine gastric mucine and bovine salivary mucine is between 30:1 and 200:1.

12. A composition as claimed in claim 11 wherein the weight ratio between porcine gastric mucine and bovine salivary mucine is in the range between 100:5 and 100:0.5.

13. A composition as claimed in claim 1 or 11 in which the mucine content of the solution is 0.2-6% by weight.

14. A composition as claimed in claim 13 in which the mucine content of the solution is 1-5% by weight.

15. A composition as claimed in claim 8 for use as an artificial saliva solution, the composition having a viscosity between 2 and 30 relative to water, as measured with an Oswald viscosimeter.

16. An artificial saliva solution as claimed in claim 15 which has a viscosity between 4 and 10.

17. An artificial saliva solution as claimed in claims 16 which contains at least one ion species found in human saliva.

18. An artificial saliva solution as claimed in claim 17 which contains a thiocyanate.

19. An artificial saliva solution as claimed in claim 18 in which the thiocyanate is present in a concentration of from 0.25 mM to 6 mM.

20. An artificial saliva solution as claimed in claim 16 which has a surface tension in the range between 40 and 60 dyn.cm.

21. A sterilized composition comprising a non-human mammalian mucine selected from the group consisting of buccal and gastrointestinal mucines and containing an oxidizing bactericide, as a preservative.

22. A composition as claimed in claim 21 which comprises porcine gastric mucine.

23. A composition as claimed in claim 21 which comprises bovine salivary mucine.

24. A composition as claimed in claim 21 which contains a combination of porcine gastric mucine and bovine salivary mucine.

25. A composition as claimed in claim 24 wherein the weight ratio between porcine gastric mucine and bovine salivary mucine in the composition is from 1:1000 to 1000:1.

26. A composition as claimed in claim 25 wherein the weight ratio between porcine gastric mucine and bovine salivary mucine is between 30:1 and 200:1.

27. A composition as claimed in claim 26 wherein the weight ratio between porcine gastric mucine and bovine salivary mucine is in the range between 100:5 and 100:0.5.

28. A composition as claimed in claim 25 which is an aqueous solution.

29. A composition as claimed in claim 25 which is a dry composition.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: John H. Lee et al.	
Appln. No.	: 09/392,243	
Filed	: September 9, 1999	Group Art Unit: 1651
Title	: PROCESSES FOR MAKING PROTEIN HYDROLYSATES FROM ANIMAL PEPTONE AND FOR PRESERVING MUCOSA	Examiner: F. Prats
Docket No.	: LL11.12-0073	

EXHIBIT C OF APPENDIX B IN BRIEF FOR APPELLANT

U.S. Patent No. 4,145,451 (the Oles patent)

United States Patent [19]
Oles

[11] **4,145,451**
[45] **Mar. 20, 1979**

[54] **PRESERVATION OF LOW ACID FOOD
PRODUCTS IN THE ABSENCE OF
CHEMICAL PRESERVATIVES**

[75] **Inventor:** John G. Oles, Glenview, Ill.

[73] **Assignee:** Kraft, Inc., Glenview, Ill.

[21] **Appl. No.:** 791,173

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[52] **U.S. Cl.** 426/321; 426/602;
426/605; 426/613; 426/589

[58] **Field of Search** 426/602, 605, 613, 589,
426/321, 271

[56]

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Primary Examiner—Jeanette M. Hunter

Attorney, Agent, or Firm—Fitch, Even, Tabin &
Luedeka

[57]

ABSTRACT

Preservation of low acid food products in the absence of chemical preservatives with the combination of acetic acid and phosphoric acid.

28 Claims, No Drawings

PRESERVATION OF LOW ACID FOOD PRODUCTS IN THE ABSENCE OF CHEMICAL PRESERVATIVES

The present invention relates generally to the preservation of food against microbiological spoilage and particularly to the preparation of food products which are resistant to yeast and mold growth. More particularly, the present invention is directed to a method for preventing spoilage of food containing low levels of acid in the absence of chemical food preservatives conventionally used to inhibit yeast and mold growth, and to such food products.

Food spoilage may result from the unwanted growth of bacteria, yeasts, and/or molds. In food products where acid is present, generally for the purpose of imparting a tart flavor, the pH is sufficiently low that bacteria that are dangerous to the public health do not grow. However, yeasts and molds do grow under these pH conditions and the present invention is described in connection with the preservation of food products against spoilage by yeast and mold. It is to be understood, however, that the present invention also affords preservation against bacterial spoilage.

It is well known that sugar and organic acids, e.g., acetic acid from vinegar, are useful for the preservation of food products, such as salad dressing, mayonnaise, and condiments. When the food is not pasteurized and chemical preservative agents, such as sodium benzoate, are omitted from the formulation, the food product must contain relatively large quantities of sugar and/or acid for preservation against yeast and mold growth.

The relationship between the requirements of sugar and acid for the preservation of food products in the absence of chemical preservatives has been reported by Bell and Etchells, Food Technology, December 1952, 468-471. In accordance with the studies of Bell and Etchells, it was determined that as the level of sugar decreased in a simulated food product, the level of acetic acid must be increased above a minimum level to preserve the food product against yeast and mold growth.

A graph was presented in the Bell and Etchells article which predicted the level of acetic acid required for a given level of sugar in the food product. This graph has been verified by extensive testing and is widely used in the pickling and salad dressing industry. The graph is commonly referred to as the "Bell-Etchells Curve." In accordance with the Bell-Etchells Curve the level of acetic acid required to stabilize a food product having low levels of sugar (5-10 percent) is in excess of 4.0 percent by weight acetic acid, based on the weight of moisture present, i.e., volume percent of acetic acid. This amount of acid produces unacceptable flavors in many food products having relatively bland flavor, for example, dressings for salads. Similarly, many bland food products become unacceptably sweet when high levels of sugar are present. Therefore, chemical preservatives have typically been used in order to preserve these food products.

It has been determined, as set forth in U.S. Pat. No. 3,955,010, to Chozianin et al., that the level of acetic acid required in a high moisture low fat emulsified oil dressing for preservation against bacterial growth can be greatly reduced if the level of bacterial nutrient ingredients is reduced to a level of less than about 1.0 percent by weight of the composition. However, the oil

dressing compositions of the Chozianin et al. patent are not completely preserved against spoilage in the absence of a chemical preservative such as sodium benzoate.

In accordance with the present invention, it has been discovered that food products such as dressings for salad that contain low acid levels may be preserved against spoilage in the absence of chemical preservatives by including a small but effective amount of phosphoric acid in the food composition.

Accordingly, it is a principal object of the present invention to provide a method for the preservation of food products against spoilage in the absence of chemical preservatives.

It is another object of the present invention to provide food products having reduced levels of acetic acid or other organic food acid at given sugar contents which are preserved against spoilage in the absence of chemical preservatives.

It is a further object of the present invention to provide dressings for salads containing low levels of acetic acid and phosphoric acid which are stable against spoilage in the absence of preservative agents.

These and other objects of the invention will become more apparent from the following detailed description.

In accordance with various features of the present invention, food compositions are prepared which are stable against spoilage without the presence of chemical preservatives, but which contain less acetic acid than has been previously thought necessary. The food compositions of the present invention contain a synergistic combination of acetic acid or other organic food acid and phosphoric acid. The total level of acid is below the total level of acid previously predicted to preserve food products for any given level of sugar present in the food product.

The method of the present invention provides for the preparation of food products which are stable against spoilage in the absence of chemical preservatives. The dressing products contemplated by the present invention include oil or oilless, pourable or viscous, emulsified or nonemulsified food products commonly used as an adjunct on salads, vegetables, sandwiches, and the like. Included within such classification are products such as mayonnaise, salad dressing, and French dressing, and imitations thereof, for which federal standards have been created, as well as low calorie oilless products, including condiments, and emulsified and nonemulsified oil-containing products for which no federal standards exist.

In general, the food compositions contemplated by the present invention may have any of the ingredients listed hereinbelow at the indicated level. As used herein, percent acetic and/or phosphoric acid is expressed as weight percent based on the total moisture present. All other references to percent are to weight percent of the total composition.

Ingredient	Weight Percent
Oil	0-60
Moisture	20-96
Egg Yolk	0-20
Milk Solids Not Fat	0-15
Sweetener	0-30
Salt	0-5
Gums	0-15
Starch	0-20
Spices and Flavors	0-15
Acetic Acid	0.05-1.8

-continued

Ingredient	Weight Percent
Phosphoric Acid	0.1-1.5

A typical high oil-containing dressing for salad, which may be either pourable or semisolid, might have the following composition:

Ingredient	Weight Percent	
	Range	Specific Example
Oil	30-60	50.0
Moisture	20-50	38.65
Egg Yolk	0-8	4.0
Sweetener	0-4	2.0
Salt	0-4	1.5
Starch	0-4	0.0
Gum	0-1.5	0.75
Spices and Flavors	0-5	2.0
Acetic Acid	0.05-1.8	1.0
Phosphoric Acid	0.1-1.5	0.1

A typical low oil-containing dressing for salad, which may be either pourable or semisolid, might have the following composition:

Ingredient	Weight Percent	
	Range	Specific Example
Oil	10-15	10.0
Moisture	35-90	64.5
Sweetener	0-10	8.0
Egg Yolk	0-7	4.0
Salt	0-4	2.0
Starch	0-10	6.0
Gum	0-11	1.5
Spices and Flavors	0-5	2.8
Acetic Acid	0.05-1.8	1.0
Phosphoric Acid	0.1-1.5	0.2

A typical oilless dressing, for example, for condiments, might have the following composition:

Ingredient	Weight Percent	
	Range	Specific Example
Oil	< 1.5	1.0
Moisture	55-96	65.3
Egg Yolk	0-20	5.0
MSNF	0-15	5.0
Sweetener	0-30	10.0
Salt	0-5	2.0
Gum	0-15	1.5
Starch	0-20	6.0
Spices and Flavors	0-15	3.0
Acetic Acid	0.05-1.8	1.0
Phosphoric Acid	0.1-1.5	0.2

These formulations are presented by way of example only and other formulations for dressings for salads are well known in the art. Similarly, techniques for the manufacture of dressing products of the types described herein are well known and within the skill of the art.

The ingredients that are utilized in compositions are also well known. The oil may be any of the well known triglyceride oils derived from oil seeds, for example, corn oil, soybean oil, safflower oil, cottonseed oil, etc., or mixtures thereof. The sweetener used is typically sucrose. However, other sweeteners such as dextrose, fructose, corn syrup solids, and synthetic sweeteners are contemplated. When a nonsucrose sweetener is used, the level of use is determined based upon its sweetening power, calculated as sucrose, in accord with conventional practice.

The egg yolk may be from whole eggs, liquid egg yolk, or dried egg yolk, and may be fresh or frozen. In

the formulations herein the egg yolk content is expressed in terms of liquid egg yolk. The gums, starches, spices, and flavors that may be used are those conventionally employed for food uses. In general, if a gum is employed, the starch is omitted and vice versa. However, in some instances it may be desirable to employ both a gum and a starch to achieve a particular end result.

In accordance with the present invention, a synergistic combination of phosphoric acid and acetic acid is added to a dressing product of the type set forth above. The respective amounts of phosphoric acid and acetic acid are selected in order to provide effective preservation of the dressing product against spoilage in the absence of chemical preservatives. It has been found that the moisture content of the dressing product has an effect on the amount of the respective acids required to achieve preservation. For example, at low levels of acetic acid, based upon the moisture present, a slightly greater amount of phosphoric acid, based upon the moisture present, is required to preserve an 80 percent moisture product than is required to preserve a 40 percent moisture product, and vice versa.

It has also been found that the level of sugars in the dressing product has a bearing on the preservation of the dressing. If no sugar is present, dressings with very low quantities of both acetic and phosphoric acids are preserved whereas essentially identical dressings containing small amounts of sugar, e.g., 1 to 2.5 percent, spoil. At the other end of the sugar range, it has been found that dressing products having sugar contents greater than 17 to 18 percent and low levels of both acetic and phosphoric acid are preserved whereas similar dressings containing 10 percent sugar are not preserved.

In practice, the relative amounts of acetic and phosphoric acid employed in any food composition are selected by first selecting that amount of acetic acid which provides the desired acid or tart flavor. Knowing the amount of acetic acid in the composition, and the amount of moisture and sugar in the composition, an amount of phosphoric acid effective to preserve the composition against spoilage is added. Obviously, the procedure could be reversed, but this could lead to compositions containing excessive amounts of acetic acid with resulting harsh flavors.

The present invention is principally directed to compositions of the mayonnaise and salad dressing type. These compositions are relatively bland in flavor and have low acetic acid content in order to provide the requisite flavor. Generally the acetic acid content should not exceed 1.8 percent, preferably 1.0 percent, in the presence of phosphoric acid, in order to impart the bland flavor. It is to be understood that the upper limit of 1.8 percent acetic acid is that amount normally found in dressing products, and other systems having greater acetic acid content and which employ the combination of acetic acid and phosphoric acid to preserve the composition against spoilage in the absence of chemical preservatives are within the scope of the invention. The acetic acid is typically incorporated in the formulation as vinegar of 100-120 grain strength, i.e., 10-12 percent acetic acid.

As indicated, the amount of phosphoric acid is selected based upon the amount of acetic acid in the composition. Generally only minor amounts of phosphoric acid are required, for example, 0.1 to 0.5 percent, based

on moisture. The presence of phosphoric acid in an amount in excess of 1.5 percent may result in a composition having too low a pH and poor organoleptic and/or physical properties. Any food grade phosphoric acid may be used. Typically, 75-85 percent phosphoric acid solutions are used.

EXAMPLES

Various dressing formulations were prepared using conventional processing techniques to illustrate the present invention. The formulations are set forth in Tables I and II below. In addition, all formulations contained 5 percent egg yolk solids, 1.5 percent salt, 1 to 3 percent vegetable gums, and spices and flavors,

The ingredients were mixed together in accordance with typical practices, homogenized and/or emulsified to form a semisolid dressing, and packed into jars. No chemical preservatives were included in any of the samples.

Resistance to spoilage was determined by inoculating triplicate samples of each dressing composition with 10^4 to 10^5 mixed yeast strains per gram and by inoculating triplicate samples with 10^4 to 10^5 mixed mold strains per gram. The samples were incubated at room temperature and plate counts, using standard microbiological procedures, were made after 1, 2, and 4 weeks. The term D/C means the test was terminated because of rampant growth.

TABLE I

Sample	% Fat	40% Moisture				Fourth Week		Effective Preservation
		Weight Percent Based on Moisture		pH	% Sugar	Yeast	Mold	
		H ₃ PO ₄	HAC					
1	45.0	0.	1.6	2.82	10.0	D/C	10 ²	No
2	47.0	0.1	0.1	2.35	10.0	10 ⁵	10 ²	No
3	47.5	0.1	0.4	2.40	10.0	D/C	10 ²	No
4	47.0	0.1	0.8	2.20	10.0	10 ⁵	10	No
5	42.8	0.1	1.2	2.30	10.0	10 ⁴	10	No
6	47.2	0.1	1.6	2.30	10.0	10 ⁵	10	Yes
7	56.8	0.1	0.1	2.30	0.0	10 ⁴	10 ⁴	Yes
8	56.5	0.1	0.1	2.20	1.0	10 ⁵	10 ³	No
9	55.3	0.1	0.1	2.20	2.5	10 ⁵	10 ³	No
10	58.4	0.1	0.2	2.40	0.0	10 ³	10 ¹	Yes
11	56.6	0.1	0.2	2.00	1.0	10 ⁴	10 ³	Yes
12	55.2	0.1	0.2	2.40	2.5	10 ⁵	10 ³	No
13	46.9	0.15	0.3	2.30	10.0	10 ⁵	10 ²	Borderline
14	40.4	0.20	0.05	2.14	10.0	10 ⁴	10 ¹	Borderline
15	47.9	0.20	0.075	2.21	10.0	10 ⁵	10 ¹	Yes
16	48.2	0.20	0.10	2.22	10.0	10 ⁵	10 ²	Yes
17	46.8	0.25	0.1	2.10	10.0	10 ⁵	10 ²	Yes
18	46.5	0.3	0.05	2.10	10.0	10 ⁵	10 ²	Yes
19	46.6	0.3	0.075	2.11	10.0	10 ¹	10 ¹	Yes
20	46.2	0.3	0.1	1.80	10.0	<10	10 ¹	Yes
21	49.0	0.3	0.4	1.85	10.0	<10	<10	Yes
22	37.0	0.3	0.4	1.89	10.0	10 ⁵	10 ³	Yes
23	43.0	0.3	0.8	2.00	10.0	<10	<10	Yes
24	47.1	0.3	1.2	2.00	10.0	<10	<10	Yes
25	47.0	0.3	1.6	1.90	10.0	<10	<10	Yes
26	48.1	0.5	0.1	1.60	10.0	<10	10 ¹	Yes
27	45.4	0.5	0.4	1.63	10.0	<10	<10	Yes
28	35.6	0.5	0.8	1.75	10.0	<10	<10	Yes
29	47.3	0.5	1.2	1.70	10.0	<10	<10	Yes
30	47.8	0.5	1.6	1.70	10.0	<10	<10	Yes

with the exception of Sample 44 which has no gums.

TABLE II

80% Moisture								
Sample	% Fat	Weight Percent Based on Moisture		Fourth Week		Effective		Preservation
		H ₃ PO ₄	HAC	pH	% Sugar	Yeast	Mold	
31	.31	0.1	0.05	2.40	17.5	D/C	10 ⁴	No
32	16.6	0.1	0.1	2.40	0.	10 ⁴	10 ³	Yes
33	15.3	0.1	0.1	2.10	1.0	10 ⁵	10 ³	No
34	13.8	0.1	0.1	2.40	2.5	D/C	10 ³	No
35	6.0	0.1	0.1	2.35	10.0	D/C	10 ³	No
36	3.0	0.1	0.1	2.40	13.0	D/C	10 ³	No
37	1.5	0.1	0.1	2.50	15.0	D/C	10 ³	No
38	0.	0.1	0.1	2.33	18.9	<10	10 ³	Yes
39	14.0	0.1	0.2	2.40	0.	10 ⁵	10 ³	Yes
40	15.2	0.1	0.2	2.50	1.0	10 ⁵	10 ³	No
41	14.3	0.1	0.2	2.20	2.5	D/C	10 ³	No
42	.64	0.1	0.4	2.40	10.0	D/C	10 ³	No
43	.18	0.1	0.4	2.55	18.0	10 ⁶	10 ²	No
44	0.	0.1	0.4	2.28	19.0	10 ²	<10	Yes
45	11.6	0.1	0.8	2.41	5.34	10 ⁵	<10	No
46	.9	0.1	0.8	2.30	10.0	10 ⁴	10 ²	No
47	0.	0.1	0.8	2.30	18.5	<10	<10	Yes
48	1.3	0.1	1.2	2.30	10.0	10 ⁴	10 ¹	No
49	2.2	0.1	1.6	2.35	10.0	10 ⁴	10 ¹	No
50	7.6	0.15	0.3	2.20	10.0	10 ⁵	10 ²	No
51	7.5	0.2	0.05	2.17	10.0	10 ⁵	10 ³	Borderline
52	7.0	0.2	0.075	2.22	10.0	10 ⁶	10 ³	Yes
53	4.8	0.2	0.1	2.28	10.0	10 ⁶	10 ³	Yes
54	7.7	0.2	0.2	2.17	10.0	10 ⁴	10 ³	Yes
55	7.7	0.25	0.1	2.08	10.0	10 ⁴	10 ²	Yes
56	4.1	0.3	0.05	2.20	10.0	10 ²	10 ⁴	Yes
57	7.4	0.3	0.075	2.50	10.0	10 ³	10 ²	Yes

TABLE II-continued

TABLE 1 CONTINUED									
80% Moisture									
Weight Percent Based on Moisture									
Sample	% Fat	on Moisture		Fourth Week		Effective		Preservation	
		H ₃ PO ₄	HAC	pH	% Sugar	Yeast	Mold		
58	6.1	0.3	0.1	1.90	10.0	10 ¹	10 ³	Yes	
59	7.0	0.3	0.4	2.11	10.0	<10	<10	Yes	
60	.9	0.3	0.4	1.90	10.0	<10	10 ¹	Yes	
61	2.4	0.3	0.8	1.90	10.0	<10	<10	Yes	
62	3.0	0.3	1.2	1.90	10.0	<10	<10	Yes	
63	.9	0.3	1.6	1.90	10.0	<10	<10	Yes	
64	5.7	0.5	0.1	1.70	10.0	<10	10 ²	Yes	
65	1.3	0.5	0.4	1.70	10.0	<10	10 ¹	Yes	
66	3.4	0.5	0.8	1.70	10.0	<10	<10	Yes	
67	2.4	0.5	1.2	1.70	10.0	<10	<10	Yes	
68	2.4	0.5	1.6	1.70	10.0	<10	<10	Yes	

The synergistic effect obtained through the present invention is apparent from the fact that dressing products containing either as much as 1.6 percent acetic acid or 0.75 percent phosphoric acid (not included in the Tables) are not preserved, while similar dressing products containing 0.2 percent phosphoric acid and 0.05 or more percent acetic acid are preserved regardless of the moisture content. The effect of the amount of moisture is seen by the fact that at 40 percent moisture, 0.1 percent phosphoric acid and 1.6 percent acetic acid effect preservation (Sample 6); 0.15 percent phosphoric acid and 0.3 percent acetic acid is borderline (Sample 13); and 0.2 percent phosphoric acid and 0.05 percent acetic acid is borderline (Sample 14). However, at 80 percent moisture, 0.1 percent phosphoric acid and 1.6 percent acetic acid spoils (Sample 49); 0.15 percent phosphoric acid and 0.3 percent acetic acid spoils (Sample 50); 0.2 percent phosphoric acid and 0.05 percent acetic acid is borderline (Sample 51); and 0.2 percent phosphoric acid and 0.075 percent acetic acid is preserved (Sample 52).

The further effect of the sugar content may be seen by comparing Samples 7, 8, and 9; and 10, 11, and 12 at 40 percent moisture; and Samples 37, 38, and 39; 43 and 44; and 45, 46, and 47 at 80 percent moisture.

Samples 7, 8, and 9 reveal that when zero sugar is present in a dressing containing 40 percent moisture, preservation is achieved (Sample 7), while similar compositions containing 1 (Sample 8) and 2.5 (Sample 9) percent sugar are not preserved when 0.1 percent phosphoric acid and 0.1 percent acetic acid are present. Samples 10, 11, and 12 show that when the acetic acid level is increased to 0.2 percent in similar compositions, preservation is achieved at 0 (Sample 10) and 1 (Sample 11) percent sugar but is not achieved at 2.5 (Sample 12) percent sugar.

Samples 37 and 38 show that in high moisture compositions when the sugar is increased from 15 to 19 percent, preservation is achieved. Sample 39 confirms the results of Samples 10, 11, and 12. Samples 43 and 44 confirm the results of Samples 37 and 38 at higher acetic acid concentrations. Samples 45, 46, and 47 further confirm the fact that high sugar content dressings, i.e., those containing in excess of 18 percent by weight sugar can be effectively preserved with as little as 0.1 percent phosphoric acid and 0.1 percent acetic acid. This may be desirable in sweet dressing where a harsh acid taste is undesired. The fact that preservation is achieved at very low sugar concentrations is important from the standpoint that compositions of the type disclosed in U.S. Pat. No. 3,955,010 may be prepared without the addition of any chemical preservatives.

The present invention provides a flexible and useful method for the preservation of food products against

microbiological spoilage at reduced levels of acid without the use of a chemical preservative such as sodium benzoate. Food products can be prepared in accordance with the method of the present invention which are organoleptically desirable, bland in taste and with enhanced perception of delicate flavors.

What is claimed is:

1. A preserved food composition comprising a food and between 0 and about 60 percent by weight edible oil, between about 30 and about 96 percent by weight moisture, between 0 and about 30 percent by weight sweetener, as sucrose equivalent, balance food solids and a preserving system containing between about 0.05 and about 1.8 percent by weight, based on the total moisture content of the food composition, acetic acid, and between about 0.1 and about 1.5 percent by weight, based on the total moisture content of the food composition, phosphoric acid, the amount of phosphoric acid being based on the amount of moisture, sweetener, and acetic acid such that said food composition is preserved against microbiological spoilage in the absence of chemical preservatives.
2. A food composition in accordance with claim 1 containing at least about 0.2 percent by weight, based on moisture, phosphoric acid.
3. A food composition in accordance with claim 2 containing at least about 0.1 percent by weight, based on moisture, acetic acid.
4. A food composition in accordance with claim 3 containing between about 40 and about 80 percent moisture.
5. A salad dressing comprising between about 30 and about 60 percent by weight edible oil, between about 20 and about 50 percent by weight moisture, between 0 and about 8 percent by weight egg yolk, between 0 and about 4 percent by weight sweetener, as sucrose equivalent, between 0 and about 4 percent by weight salt, between 0 and about 4 percent by weight starch, between 0 and about 1.5 percent gum, between 0 and about 5 percent by weight spices and flavors, between about 0.05 and about 1.8 percent by weight, based on total moisture content of the food composition, acetic acid, and between about 0.1 and about 1.5 percent by weight, based on total moisture content of the food composition, phosphoric acid, said salad dressing being preserved against microbiological spoilage in the absence of chemical preservatives.
6. A salad dressing in accordance with claim 5 containing at least about 0.2 percent by weight, based on moisture, phosphoric acid.

7. A salad dressing in accordance with claim 6 containing at least about 0.1 percent by weight, based on moisture, acetic acid.

8. A salad dressing comprising between about 10 and about 15 percent by weight edible oil, between about 35 and about 90 percent by weight moisture, between 0 and about 10 percent by weight sweetener, as sucrose equivalent, between 0 and about 7 percent by weight egg yolk, between 0 and about 4 percent by weight salt, between 0 and about 10 percent by weight starch, between 0 and about 11 percent by weight gum, between 0 and about 5 percent by weight spices and flavors, between about 0.05 and about 1.8 percent by weight, based on total moisture content of the food composition, acetic acid, and between about 0.1 and about 1.5 percent by weight, based on total moisture content of the food composition, phosphoric acid, said salad dressing being preserved against microbiological spoilage in the absence of chemical preservatives.

9. A salad dressing in accordance with claim 8 containing at least about 0.2 percent by weight, based on moisture, phosphoric acid.

10. A salad dressing in accordance with claim 9 containing at least about 0.1 percent by weight, based on moisture, acetic acid.

11. A dressing composition comprising less than about 1.5 percent by weight edible oil, between about 55 and about 96 percent by weight moisture, between 0 and about 20 percent by weight egg yolk, between 0 and about 15 percent by weight milk solids nonfat, between 0 and about 30 percent by weight sweetener, as sucrose equivalent, between 0 and about 5 percent by weight salt, between 0 and about 15 percent by weight gum, between 0 and about 20 percent by weight starch, between 0 and about 15 percent by weight spices and flavors, between 0.05 and 1.8 percent by weight, based on total moisture content of the food composition, acetic acid, and between 0.01 and 1.5 percent by weight, based on the total moisture content of the food composition, phosphoric acid, said dressing being preserved against microbiological spoilage in the absence of chemical preservatives.

12. A dressing in accordance with claim 11 containing at least about 0.2 percent by weight, based on moisture, phosphoric acid.

13. A dressing in accordance with claim 12 containing at least about 0.1 percent by weight, based on moisture, acetic acid.

14. A method of preparing a preserved food composition containing a food and between 0 and about 60 percent by weight edible oil, between about 20 and about 96 percent by weight moisture, and between 0 and about 30 percent by weight sweetener, as sucrose equivalent balance food solids, against microbiological spoilage in the absence of chemical preservatives, comprising incorporating in said food composition an effective amount of a mixture of between about 0.05 and about 1.8 percent by weight acetic acid, based on total moisture content of the food composition, and between about 0.1 and about 1.5 percent by weight phosphoric acid, based on total moisture content of the food composition.

15. A method in accordance with claim 14 wherein at least about 0.2 percent by weight, based on moisture, phosphoric acid is incorporated in said food composition.

16. A method in accordance with claim 15 wherein at least about 0.1 percent by weight, based on moisture, acetic acid is incorporated in said food composition.

17. A method of preserving a salad dressing containing between about 30 and about 60 percent by weight edible oil, between about 20 and about 50 percent by weight moisture, between 0 and about 30 percent by weight sweetener, as sucrose equivalent, between 0 and about 8 percent by weight egg yolk, between 0 and about 4 percent by weight salt, between 0 and about 4 percent by weight starch, between 0 and about 1.5 percent by weight gum, and between 0 and about 5 percent by weight spices and flavors, against microbiological spoilage in the absence of chemical preservatives comprising incorporating in said salad dressing an effective amount of a mixture of between about 0.05 and about 1.8 percent by weight acetic acid, based on total moisture content of the food composition, and between about 0.1 and about 1.5 percent by weight phosphoric acid, based on total moisture content of the food composition.

18. A method in accordance with claim 17 wherein at least about 0.2 percent by weight, based on moisture, phosphoric acid is incorporated in said salad dressing.

19. A method in accordance with claim 18 wherein at least about 0.1 percent by weight, based on moisture, acetic acid is incorporated in said salad dressing.

20. A method of preserving a salad dressing containing between about 10 and about 15 percent by weight edible oil, between about 35 and about 90 percent by weight moisture, between 0 and about 10 percent by weight sweetener, as sucrose equivalent, between 0 and about 7 percent by weight egg yolk, between 0 and about 4 percent by weight salt, between 0 and about 10 percent by weight starch, between 0 and about 11 percent by weight gum, and between 0 and about 15 percent by weight spices and flavors against microbiological spoilage in the absence of chemical preservatives comprising incorporating in said salad dressing an effective amount of a mixture of between about 0.05 and about 1.8 percent by weight acetic acid, based on total moisture content of the food composition, and between about 0.1 and about 1.5 percent by weight phosphoric acid, based on total moisture content of the food composition.

21. A method in accordance with claim 20 wherein at least about 0.2 percent by weight, based on moisture, phosphoric acid is incorporated in said salad dressing.

22. A method in accordance with claim 21 wherein at least about 0.1 percent by weight, based on moisture, acetic acid is incorporated in said salad dressing.

23. A method of preserving a dressing containing less than about 1.5 percent by weight edible oil, between about 55 and about 96 percent by weight moisture, between 0 and about 30 percent by weight sweetener, as sucrose equivalent, between 0 and about 20 percent by weight egg yolk, between 0 and about 5 percent by weight salt, between 0 and about 15 percent by weight milk solids nonfat, between 0 and about 20 percent by weight starch, between 0 and about 15 percent by weight gum, and between 0 and about 15 percent by weight spices and flavors against microbiological spoilage in the absence of chemical preservatives comprising incorporating in said dressing an effective amount of a mixture of between about 0.05 and about 1.8 percent by weight acetic acid, based on total moisture content of the food composition, and between about 0.1 and about

1.5 percent by weight phosphoric acid, based on total moisture content of the food composition.

24. A method in accordance with claim 23 wherein at least about 0.2 percent by weight, based on moisture, phosphoric acid is incorporated in said dressing.

25. A method in accordance with claim 24 wherein at least about 0.1 percent by weight, based on moisture, acetic acid is incorporated in said dressing.

26. A dressing composition comprising about 50 percent by weight edible oil, about 4 percent by weight egg yolk, about 2 percent by weight sweetener, calculated as sucrose, about 1.5 percent by weight salt, about 0.75 percent by weight gum, about 2 percent by weight spices and flavors, about 1.0 percent by weight, based on total moisture content of the food composition, acetic acid, about 0.1 percent by weight, based on total moisture content of the food composition, phosphoric acid, and the balance moisture, said dressing containing no chemical preservatives.

27. A dressing composition comprising about 10 percent by weight edible oil, about 8 percent by weight sweetener, calculated as sucrose, about 4 percent by

weight egg yolk, about 2 percent by weight salt, about 6 percent by weight starch, about 1.5 percent by weight gum, about 1.5 percent by weight spices and flavors, about 1 percent by weight, based on total moisture content of the food composition, acetic acid, about 0.2 percent by weight, based on total moisture content of the food composition, phosphoric acid, and the balance moisture, said dressing containing no chemical preservatives.

28. A dressing composition comprising about 1 percent by weight edible oil, about 5 percent by weight egg yolk, about 5 percent by weight milk solids nonfat, about 10 percent by weight sweetener, calculated as sucrose, about 2 percent by weight salt, about 1.5 pounds by weight gum, about 6 percent by weight starch, about 3 percent by weight spices and flavors, about 1 percent by weight, based on total moisture content of the food composition, acetic acid, about 0.2 percent by weight, based on moisture, phosphoric acid, and the balance moisture, said dressing containing no chemical preservatives.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: John H. Lee et al.	
Appln. No.	: 09/392,243	
Filed	: September 9, 1999	Group Art Unit: 1651
Title	: PROCESSES FOR MAKING PROTEIN HYDROLYSATES FROM ANIMAL PEPTONE AND FOR PRESERVING MUCOSA	Examiner: F. Prats
Docket No.	: LL11.12-0073	

EXHIBIT D OF APPENDIX B IN BRIEF FOR APPELLANT

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Third Edition

JAMES M. JAY
Wayne State University

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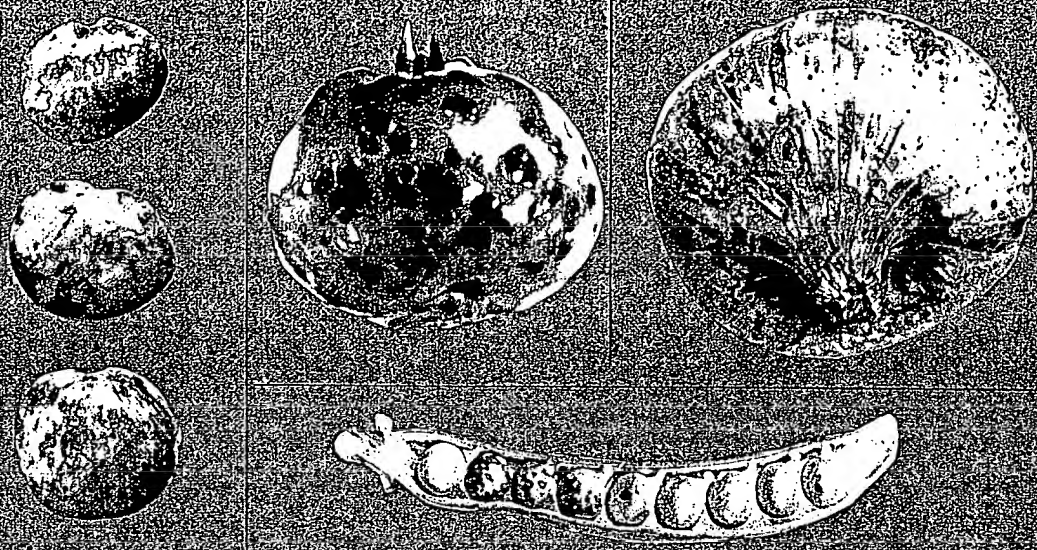
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Modern Food Microbiology



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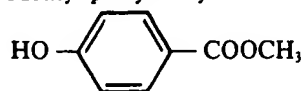
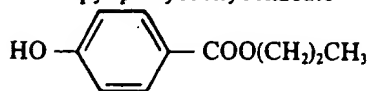
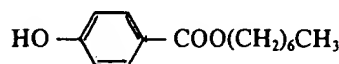
11.

FOOD PRESERVATION WITH CHEMICALS

The use of chemicals to prevent or delay the spoilage of foods derives in part from the fact that such compounds have been used with great success in the treatment of diseases of man, animals, and plants. This is not to imply that any and all chemotherapeutic compounds can or should be used as food preservatives. On the other hand, there are some chemicals of value as food preservatives that would be ineffective or too toxic as chemotherapeutic compounds. With the exception of certain antibiotics, none of the presently used food preservatives find any real use as chemotherapeutic compounds in man and animals. While a large number of chemicals have been described that show potential as food preservatives, only a relatively small number are allowed in food products. This is due in large part to the strict rules of safety adhered to by the Food and Drug Administration (FDA), and to a lesser extent to the fact that not all compounds that show antimicrobial activity in vitro do so when added to certain foods. Below are described those compounds most widely used, their modes of action where known, and the types of foods in which they are used. Those chemical preservatives generally recognized as safe (GRAS) are summarized in Table 11-1.

BENZOIC ACID AND THE PARABENS

Benzoic acid (C_6H_5COOH) and its sodium salt ($C_6H_5NaO_2$) along with the esters of *p*-hydroxybenzoic acid (parabens) are considered together in this section. Sodium benzoate was the first chemical preservative permitted in foods by the U.S. Food and Drug Administration, and it continues in wide use today in a large number of foods. Its approved derivatives have structural formulas as noted:

Methylparaben
Methyl *p*-HydroxybenzoatePropylparaben
Propyl *p*-HydroxybenzoateHeptylparaben
n-Heptyl-*p*-hydroxybenzoate.

The antimicrobial activity of benzoate is related to pH, the greatest activity being at low pH values. The antimicrobial activity resides in the undissociated molecule (see below). These compounds are most active at the lowest pH values of foods and essentially ineffective at neutral values. The pK of benzoate is 4.20 and at a pH of 4.00, 60% of the compound is undissociated, while at a pH of 6.0 only 1.5% is undissociated. This results in the restriction of benzoic acid and its sodium salts to high-acid products such as apple cider, soft drinks, tomato catsup, and salad dressings. High acidity alone is generally sufficient to prevent growth of bacteria in these foods, but not that of certain molds and yeasts. As used in acidic foods, benzoate acts essentially as a mold and yeast inhibitor although it is effective against some bacteria in the 50–500 ppm range. Against yeasts and molds at around pH 5.0–6.0, from 100–500 ppm are effective in inhibiting the former, while for the latter from 30–300 ppm are inhibitory.

In foods such as fruit juices, benzoates may impart disagreeable tastes at the maximum level of 0.1%. The taste has been described as being "peppery" or burning.

As noted above, the three parabens that are permissible in foods in the United States are heptyl-, methyl-, and propyl-, while butyl- and ethylparabens are permitted in food in certain other countries. As esters of *p*-hydroxybenzoic acid, they differ from benzoate in their antimicrobial activity in being less sensitive to pH. Although not as many data have been presented on heptylparaben, it appears to be quite effective against microorganisms, with 10–100 ppm effecting complete inhibition of some gram-positive and gram-negative bacteria. Propylparaben is more effective than methylparaben on a ppm basis, with up to 1,000 ppm of the former and 1,000–4,000 ppm of the latter needed for bacterial inhibition, with gram-positive bacteria being more susceptible than gram negatives to the parabens in general (20). Heptylparaben has been reported to be effective against the malo-lactic bacteria. In a reduced-broth medium, 100 ppm propylparaben delayed germination and toxin production by *C. botulinum* type A, while 200 ppm effected inhibition up to 120 h at 37°C (100). In the case of methylparaben, 1,200 ppm were required for inhibition similar to that for the propyl- analog.

The parabens appear to be more effective against molds than against yeasts. As in the case of bacteria, the propyl- derivative appears to be the most effective where 100 ppm or less are capable of inhibiting some yeasts

Table 11-1

Preservatives

Propionic
propionatesSorbic acid
sorbatesBenzoic acid
benzoatesParabens^aSO₂/sulfiteEthylene/
propylene
oxides^cSodium
diacetate
Dehydroacetic
acidSodium nitrite
Caprylic acid
Ethyl formateGRAS (General
Act as amendatory)^a Methyl-, propyl-^b Heptyl ester-^c May be involved^d As formic acidand molds,
ppm, respectively

Like benzoates, parabens are permissible in beers to a limited extent in beverages. Their activity is not affected by pH as no dissociation occurs up to 8.0. F (20).

Table 11-1. Summary of some GRAS chemical food preservatives.

Preservatives	Maximum tolerance	Organisms affected	Foods
Propionic acid/propionates	0.32%	Molds	Bread, cakes, some cheeses, rope inhibitor in bread dough
Sorbic acid/sorbates	0.2%	Molds	Hard cheeses, figs, syrups, salad dressings, jellies, cakes
Benzoic acid/benzoates	0.1%	Yeasts and molds	Margarine, pickle relishes, apple cider, soft drinks, tomato catsup, salad dressings
Parabens ^a	0.1% ^b	Yeasts and molds	Bakery products, soft drinks, pickles, salad dressings
SO ₂ /sulfites	200–300 ppm	Insects, micro-organisms	Molasses, dried fruits, wine making, lemon juice (not to be used in meats or other foods recognized as sources of thiamine)
Ethylene/propylene oxides ^c	700 ppm	Yeasts, molds, vermin	Fumigant for spices, nuts
Sodium diacetate	0.32%	Molds	Bread
Dehydroacetic acid	65 ppm	Insects	Pesticide on strawberries, squash
Sodium nitrite ^c	120 ppm	Clostridia	Meat-curing preparations
Caprylic acid	—	Molds	Cheese wraps
Ethyl formate	15–200 ppm ^d	Yeasts and molds	Dried fruits, nuts

GRAS (Generally Recognized As Safe) per Section 201 (32)(s) of the U.S. Federal Food, Drug, and Cosmetic Act as amended.

^a Methyl-, propyl-, and heptyl-esters of *p*-hydroxybenzoic acid.

^b Heptyl ester—12 ppm in beers; 20 ppm in noncarbonated and fruit-based beverages.

^c May be involved in mutagenesis and/or carcinogenesis.

^d As formic acid.

and molds, while for heptyl- and methylparabens, 50–200 and 500–1,000 ppm, respectively, are required.

Like benzoic acid and its sodium salt, the methyl- and propylparabens are permissible in foods up to 0.1% while heptylparaben is permitted in beers to a maximum of 12 ppm, and up to 20 ppm in fruit drinks and beverages. The *pK* for these compounds is around 8.47, and their antimicrobial activity is not increased to the same degree as for benzoate with the lowering of pH as noted above. They have been reported to be effective at pH values up to 8.0. For a more thorough review of these preservatives, see Davidson (20).

Similarities between the modes of action of benzoic and salicylic acids have been noted (8). Both compounds, when taken up by respiring microbial cells, were found to block the oxidation of glucose and pyruvate at the acetate level in *Proteus vulgaris*. With *P. vulgaris*, benzoic acid caused an increase in the rate of O_2 consumption during the first part of glucose oxidation (8). The benzoates, like propionate and sorbate, have been shown to act against microorganisms by inhibiting the cellular uptake of substrate molecules (36). The stage of endospore germination most sensitive to benzoate is noted in Fig. 11-1.

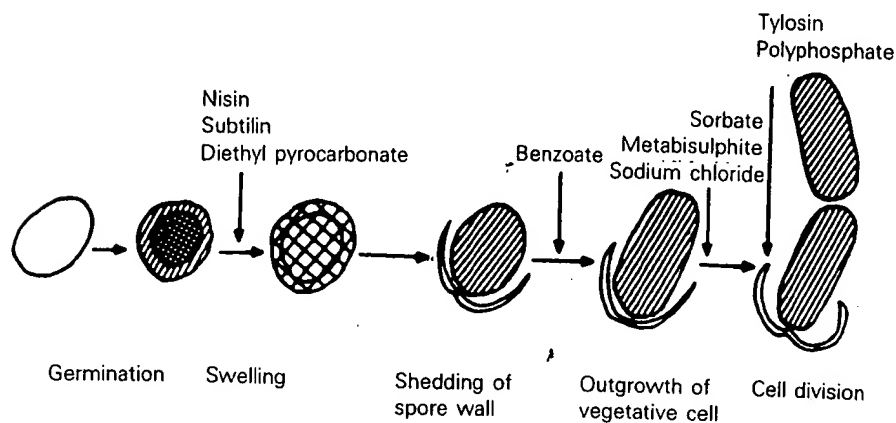


Fig. 11-1. Diagrammatic representation of growth of an endospore into vegetative cells showing stages arrested by minimum inhibitory concentrations of some food preservatives (40).

The undissociated form is essential to the antimicrobial activity of benzoate as well as for other lipophilic acids such as sorbate and propionate, as previously noted. In this state, these compounds are soluble in the cell membrane and act apparently as proton ionophores (41). As such, they facilitate proton leakage into cells and thereby increase energy output of cells to maintain their usual internal pH. With the disruption in membrane activity, amino acid transport is adversely affected (41).

SORBIC ACID

Sorbic acid ($CH_3CH=CHCH=CHCOOH$) is employed as a food preservative usually as the calcium, sodium, or potassium salt. These compounds are permissible in foods at levels not to exceed 0.2%. Like sodium benzoate, they are more effective in acid foods than in neutral foods and tend to be on par with the benzoates as fungal inhibitors. Sorbic acid works best below pH 6.0 and is generally ineffective > pH 6.5. These compounds are more effective than sodium benzoate between pH 4.0–6.0. At pH values of 3.0 and below, the sorbates are slightly more effective than the propionates

but about the same as sodium benzoate. The pK of sorbate is 4.80 and at a pH of 4.0, 86% of the compound is undissociated while at a pH of 6.0 only 6% is undissociated. Sorbic acid can be employed in cakes at higher levels than propionates without imparting flavor to the product (79).

The sorbates are primarily effective against molds and yeasts but research during the past decade has shown them to be effective against a wide range of bacteria. In general, the catalase-positive cocci are more sensitive than the catalase negatives, and aerobes are more sensitive than anaerobes. The resistance of the lactic acid bacteria to sorbate, especially at pH 4.5 or above, permits its use as a fungistat in products that undergo lactic fermentations. Its effectiveness has been shown against *S. aureus*, salmonellae, coliforms, psychrotrophic spoilage bacteria (especially the pseudomonads), and *V. parahaemolyticus*. Against the latter organism, concentrations as low as 30 ppm have been shown to be effective. Shelf-life extensions have been obtained by use of sorbates on fresh poultry meat, vacuum-packaged poultry products, fresh fish, and perishable fruits. For further information, see nitrite-sorbate combinations below, and the review by Sofos and Busta (112).

The sorbates have been studied by a large number of groups for use in meat products in combination with nitrites. Bacon formulations that contain 120 ppm NaNO_2 without sorbate yield products that maintain their desirable organoleptic qualities in addition to being protected from *C. botulinum* growth. When 0.26% (2,600 ppm) potassium sorbate is added along with 40 ppm nitrite, no significant differences are found in the organoleptic qualities or in botulinal protection ([57] and Stevenson and Price, 1976, cited in [87]). The combination of 40 ppm NaNO_2 and 0.26% potassium sorbate (along with 550 ppm sodium ascorbate or sodium erythroate) was proposed by the U.S. Department of Agriculture (USDA) in 1978 but postponed in 1979. The later action was prompted not by the failure of the reduced nitrite level in combination with sorbate but because of taste panel results that characterized finished bacon as having "chemical"-like flavors and producing prickly mouth sensations (3). The combination of sorbate plus reduced nitrite has been shown to be effective in a variety of cured meat products against not only *C. botulinum* but other bacteria such as *S. aureus*. (For further information, see nitrite section below, and reviews by Sofos and Busta [112], Tompkin [123], and Liewen and Marth [73].)

The widest use of sorbates is as fungistats in products such as cheeses, bakery products, fruit juices, beverages, salad dressings, and the like. With molds, inhibition has been reported to be due to inhibition of the dehydrogenase enzyme system (24), and to the inhibition of cellular uptake of substrate molecules such as amino acids (see benzoic acid section above), phosphate, organic acids, and so on (36). A number of other possible inhibitory mechanisms have been presented by various researchers. Against germinating endospores, sorbate prevents the outgrowth of vegetative cells (Fig. 11-1).

With respect to toxicity, sorbic acid is metabolized in the body to CO_2 and H_2O in the same manner as fatty acids normally found in foods (26).

THE PROPIONATES

Propionic acid is a three-carbon organic acid with the following structure: $\text{CH}_3\text{CH}_2\text{COOH}$. This acid and its calcium and sodium salts are permitted in breads, cakes, certain cheeses, and other foods primarily as a mold inhibitor. Propionic acid is employed also as a "rope" inhibitor in bread dough. The tendency toward dissociation is low with this compound and its salts, and these compounds are consequently active in low-acid foods. They tend to be highly specific against molds, with the inhibitory action being primarily fungistatic rather than fungicidal.

With respect to the antimicrobial mode of action of propionates, they act in a manner similar to that of benzoate and sorbate. The pK of propionate is 4.87 and at a pH of 4.00, 88% of the compound is undissociated, while at a pH of 6.0, only 6.7% remains undissociated. The undissociated molecule of this lipophilic acid is necessary for its antimicrobial activity. The mode of action of propionic acid is noted above with benzoic acid. See also section below on medium-chain fatty acids and esters, and review by Doores (28) for further information.

SULFUR DIOXIDE AND SULFITES

Sulfur dioxide (SO_2) and the sodium and potassium salts of sulfite ($=\text{SO}_3$), bisulfite ($=\text{HSO}_3$), and metabisulfite ($=\text{S}_2\text{O}_5$) all appear to act similarly and are here treated together. Sulfur dioxide is used in its gaseous or liquid form, or in the form of one or more of its neutral or acid salts on dried fruits, in lemon juice, molasses, wines, fruit juices, and others. The parent compound has been used as a food preservative since ancient times. Its use as a meat preservative in the United States dates back to at least 1813; however, it is not permitted in meats or other foods recognizable as sources of thiamine. While SO_2 possesses antimicrobial activity, it is also used in certain foods as an antioxidant.

The predominant ionic species of sulfurous acid depends upon pH of milieu with SO_2 being favored by $\text{pH} < 3.0$, HSO_3^- by pH between 3.0 and 5.0, and SO_3^{2-} $>$ pH 6.0 (86). SO_2 has pKs of 1.76 and 7.2. The sulfites react with various food constituents including nucleotides, sugars, disulfide bonds, and others:

With regard to its effect on microorganisms, SO_2 is bacteriostatic against *Acetobacter* spp. and the lactic acid bacteria at low pH, concentrations of 100 to 200 ppm being effective in fruit juices and beverages. It is bactericidal at higher concentrations. When added to temperature-abused comminuted pork, 100 ppm of SO_2 or higher were required to effect significant inhibition of spores of *C. botulinum* at target levels of 100 spores/g (127). The source

of SO_2 was sodium metabisulfite. Employing the same salt to achieve an SO_2 concentration of 600 ppm, Banks and Board (2) found that growth of salmonellae and other Enterobacteriaceae were inhibited in British fresh sausage. The most sensitive bacteria were eight salmonellae serovars, which were inhibited by 15–109 ppm at pH 7.0, while *Serratia liquefaciens*, *S. marcescens*, and *Hafnia alvei* were the most resistant, requiring 185–270 ppm free SO_2 in broth.

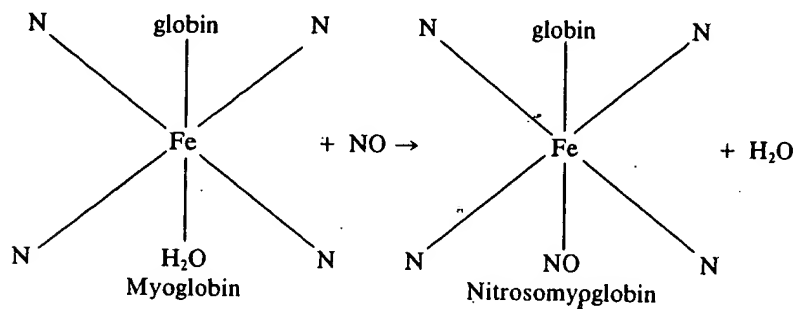
Yeasts are intermediate to acetic and lactic acid bacteria and molds in their sensitivity to SO_2 , and the more strongly aerobic species are generally more sensitive than the more fermentative species (64). Sulfurous acid at levels of 0.2–20 ppm was effective against some yeasts, including *Saccharomyces*, *Pichia*, and *Candida*, while *Zygosaccharomyces bailii* required up to 230 ppm for inhibition in certain fruit drinks at pH 3.1 (76). Yeasts can actually form SO_2 during juice fermentation—some *S. carlsbergensis* and *S. bayanus* strains produce up to 1,000 and 500 ppm, respectively (86). Molds such as *Botrytis* can be controlled on grapes by periodic gassing with SO_2 , and bisulfite can be used to destroy aflatoxins (29). Both aflatoxins B_1 and B_2 can be reduced in corn (44, 82). Sodium bisulfite was found to be comparable to propionic acid in its antimicrobial activity in corn containing up to 40% moisture (44).

Although the actual mechanism of action of SO_2 is not known, several possibilities have been suggested, each supported by some experimental evidence. One suggestion is that the undissociated sulfurous acid or molecular SO_2 is responsible for the antimicrobial activity. Its greater effectiveness at low pH tends to support this. Vas and Ingram (129) suggested the lowering of pH of certain foods by addition of acid as a means of obtaining greater preservation with SO_2 . It has been suggested that the antimicrobial action is due to the strong reducing power that allows these compounds to reduce oxygen tension to a point below that at which aerobic organisms can grow, or by direct action upon some enzyme system. SO_2 is also thought to be an enzyme poison, inhibiting growth of microorganisms by inhibiting essential enzymes. Its use in the drying of foods to inhibit enzymatic browning is based upon this assumption. Since the sulfites are known to act on disulfide bonds, it may be presumed that certain essential enzymes are affected and that inhibition ensues. The sulfites do not inhibit cellular transport. It may be noted from Fig. 11-1 that metabisulfite acts on germinating endospores during the outgrowth of vegetative cells.

NITRITES AND NITRATES

Sodium nitrate (NaNO_3) and sodium nitrite (NaNO_2) are used in curing formulae for meats since they stabilize red meat color, inhibit some spoilage and food poisoning organisms, and contribute to flavor development. The role of NO_2 in cured meat flavor has been reviewed by Gray and Pearson (43). NO_2 has been shown to disappear both on heating and storage. It

should be recalled that many bacteria are capable of utilizing nitrate as an electron acceptor and in the process effect its reduction to nitrite. The nitrite ion is by far the more important of the two in preserved meats. This ion is highly reactive and is capable of serving both as a reducing and an oxidizing agent. In an acid environment, it ionizes to yield nitrous acid (3HONO). The latter further decomposes to yield nitric oxide (NO), which is the important product from the standpoint of color fixation in cured meats. Ascorbate or erythrobrate acts also to reduce NO_2 to NO . Nitric oxide reacts with myoglobin under reducing conditions to produce the desirable red pigment nitrosomyoglobin, as shown in the following (see also Table 9-9):



When the meat pigment exists in the form of **oxymyoglobin**, as would be the case for comminuted meats, this compound is first oxidized to **metmyoglobin** (brown color). Upon the reduction of the latter, nitric oxide reacts to yield nitrosomyoglobin. Since nitric oxide is known to be capable of reacting with other porphyrin-containing compounds such as catalase, peroxidases, cytochromes, and others, it is conceivable that some of the antibacterial effects of nitrites against aerobes may be due to this action (the mechanism is discussed below). It has been shown that the antibacterial effect of NO_2 increases as pH is lowered within the acid range, and this effect is accompanied by an overall increase in the undissociated HNO_2 (13).

Organisms affected

Although the single microorganism of greatest concern relative to nitrite inhibition is *C. botulinum*, the compound has been evaluated as an antimicrobial for other organisms. During the late 1940s it was evaluated as a fish preservative and found to be somewhat effective but generally only at low pH. It is effective against *S. aureus* at high concentrations and, again, the effectiveness increases as pH is lowered. The compound is generally ineffective against Enterobacteriaceae, including the salmonellae, and against the lactic acid bacteria, although some effects are noted in cured and in vacuum-packaged meats and are probably caused by the interaction of nitrite with other environmental parameters rather than to nitrite alone.

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Nitrite is added to cheeses in some countries to control gassiness caused by *Clostridium butyricum* and *C. tyrobutyricum*. It is effective against other clostridia including *C. sporogenes* and *C. perfringens*, which are often employed in laboratory studies to assess potential antitoxigenic effects not only of nitrites but of other inhibitors that might have value as nitrite adjuncts or sparing agents.

The Perigo factor

The almost total absence of botulism in cured, canned, and vacuum-packed meats and fish products led some investigators in the mid-1960s to seek reasons as to why meat products that contained viable endospores did not become toxic. Employing culture medium, it was shown in 1967 that about ten times more nitrite was needed to inhibit clostridia if it were added after instead of before the medium was autoclaved. It was concluded that the heating of the medium with nitrite produced a substance or agent about ten times more inhibitory than nitrite alone (89, 90). This agent is referred to as the Perigo factor. The existence of this factor or effect has been confirmed by some and questioned by others. While the Perigo factor may be questionable in cured and perishable cured meats, the evidence for an inhibitory factor in culture media involving nitrite, iron, and —SH groups is more conclusive (123).

The factor does not develop in all culture media, and heating to at least 100°C is necessary for its development, although some activity develops in meats when heated to as low as 70°C. The Perigo factor is dialyzable from some culture media and meat suspensions but not from other media (62). It is not found in filter-sterilized solutions of the same medium with nitrite added (104). It has been shown that if meat is added to a medium containing the Perigo factor, the inhibitory activity is lost (63). For this reason, some Canadian workers call the inhibitor that is formed in meat the "Perigo-type factor" (14).

It is this inhibitory or antitoxigenic effect that results from the heat processing or smoking of certain meat and fish products containing nitrite that warrants the continued use of nitrite in such products. The antitoxigenic activity of nitrite in cured meats is of greater public health importance than the facts of color and flavor development. For the latter, initial nitrite levels as low as 15 to 50 ppm have been reported to be adequate for various meat products including Thuringer sausage (25). Nitrite levels of 100 ppm or more have been found to make for maximum flavor and appearance in fermented sausages (70). The antitoxigenic effect requires at least 120 ppm for bacon (9, 17), comminuted cured ham (16), and canned, shelf-stable luncheon meat (14). Many of these canned products are given a low heat process (F_0 of 0.1–0.6).

Interaction with cure ingredients and other factors

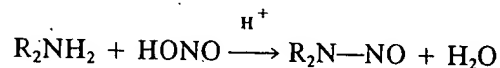
The interplay of all ingredients and factors involved in heat-processed, cured meats on antitoxigenic activity was noted over 20 years ago by Riemann

(98), and several other investigators have pointed out that curing salts in semipreserved meats are more effective in inhibiting heat-injured spores than noninjured (31, 103). With brine and pH alone, higher concentrations of the former are required for inhibition as pH increases, and Chang et al. (14) suggested that the inhibitory effect of salt in shelf-stable canned meats against heat-injured spores may be more important than the Perigo-type factor. With smoked salmon inoculated with 10^2 spores/g of *C. botulinum* types A and E and stored in O_2 -impermeable film, 3.8 and 6.1% water-phase NaCl alone inhibited toxin production in 7 days by types E and A, respectively (87). With 100 ppm or more of NO_2 , only 2.5% NaCl was required for inhibition of toxin production by type E, and for type A 3.5% NaCl + 150 ppm $NaNO_2$ was inhibitory. With longer incubations or larger spore inocula, more NaCl or $NaNO_2$ is needed.

The interplay of NaCl, $NaNO_2$, $NaNO_3$, isoascorbate, polyphosphate, thermal process temperatures, and temperature/time of storage on spore outgrowth and germination in pork slurries has been studied extensively by Roberts et al. (101), who found that significant reductions in toxin production could be achieved by increasing the individual factors noted. It is well known that low pH is antagonistic to growth and toxin production by *C. botulinum*, whether the acidity results from added acids or the growth of lactic acid bacteria. When 0.9% sucrose was added to bacon along with *Lactobacillus plantarum*, only one of forty-nine samples became toxic after 4 weeks, while with sucrose and no lactobacilli, fifty of fifty-two samples became toxic in 2 weeks (119). When 40 ppm nitrite was used alone, forty-seven of fifty samples became toxic after 2 weeks but when 40 ppm nitrite was accompanied by 0.9% sucrose and an inoculum of *L. plantarum*, none of thirty became toxic. While this was most likely a direct pH effect, other factors may have been involved (see section on lactic antagonism in Chapter 16). In more recent studies, bacon was prepared with 40 or 80 ppm $NaNO_2$ + 0.7% sucrose followed by inoculation with *Pediococcus acidilactici*. When inoculated with *C. botulinum* types A and B spores, vacuum-packaged, and incubated up to 56 days at 27°C, the bacon was found to have greater antibotulinal properties than control bacon prepared with 120 ppm $NaNO_2$ but not sucrose or lactic inoculum (118). Bacon prepared by the above formulation, called the Wisconsin process, was preferred by a sensory panel to that prepared by the conventional method (117). The Wisconsin process employs 550 ppm of sodium ascorbate or sodium erythrobate, as does the conventional process.

Nitrosamines

When nitrite reacts with secondary amines, nitrosamines are formed, and many are known to be carcinogenic. The generalized way in which nitrosamines may form is as follows:

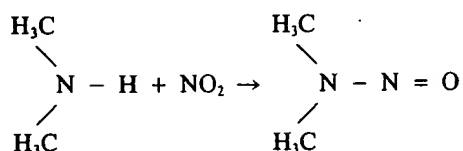


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The amine dimethylamine reacts with nitrite to form N-nitrosodimethylamine:



In addition to secondary amines, tertiary amines and quaternary ammonium compounds also yield nitrosamines with nitrite under acidic conditions. Nitrosamines have been found in cured meat and fish products at low levels (for reviews, see 19, 42).

It has been shown that lactobacilli, group D streptococci, clostridia, and other bacteria will nitrosate secondary amines with nitrite at neutral pH values (48). The fact that nitrosation occurred at near neutral pH values was taken to indicate that the process was enzymatic, although no cell-free enzyme was obtained (49). Several species of streptococci including *S. faecalis*, *S. faecium*, and *S. lactis* have been shown to be capable of forming nitrosamines, but the other lactic acid bacteria and pseudomonads tested did not (18). These investigators found no evidence for an enzymatic reaction. *S. aureus* and halobacteria obtained from Chinese salted marine fish (previously shown to contain nitrosamines) produced nitrosamines when inoculated into salted fish homogenates containing 40 ppm of nitrate and 5 ppm nitrite (34).

Nitrite-sorbate and other nitrite combinations

In an effort to reduce the potential hazard of N-nitrosamine formation in bacon, the USDA in 1978 reduced the input NO_2 level for bacon to 120 ppm and set a 10 ppb maximum level for nitrosamines. While 120 ppm nitrite along with 550 ppm sodium ascorbate or sodium erythorbate is adequate to reduce the botulism hazard, it is desirable to reduce nitrite levels even further if protection against botulinal toxin production can be achieved. To this end, a proposal to allow the use of 40 ppm nitrite in combination with 0.26% potassium sorbate for bacon was made in 1978 but rescinded a year later when taste panel studies revealed undesirable effects. Meanwhile, many groups of researchers have shown that 0.26% sorbate in combination with 40 or 80 ppm nitrite is effective in preventing botulinal toxin production. Extensive reviews of these studies have been provided to which the reader is referred for more detailed information (77, 114, 123).

In an early study of the efficacy of 40 ppm nitrite + sorbate to prevent or delay botulinal toxin production in commercial-type bacon, Ivey et al. (57) used an inoculum of 1,100 types A and B spores/g and incubated the product at 27°C for up to 110 days. Time for the appearance of toxic samples when neither nitrite nor sorbate was used was 19 days. With 40 ppm nitrite and no sorbate, toxic samples appeared in 27 days, and for samples containing 40 ppm nitrite + 0.26% sorbate or no nitrite and 0.26% sorbate, > 110

days were required for toxic samples. This reduced nitrite level resulted in lower levels of nitrosopyrrolidine in cooked bacon. Somewhat different findings were reported by Sofos et al. (Table 11-2), with 80 ppm nitrite being required for the absence of toxigenic samples after 60 days. In addition to its inhibitory effects on *C. botulinum*, sorbate slows the depletion of nitrite during storage (113).

The effect of isoascorbate is to enhance nitrite inhibition by sequestering iron, although under some conditions it may reduce nitrite efficiency by causing a more rapid depletion of residual nitrite (124, 126). EDTA at 500 ppm appears to be even more effective than erythroate in potentiating the nitrite effect, but only limited studies have been reported. Another chelate, 8-hydroxyquinoline, has been evaluated as a nitrite-sparing agent. When 200 ppm were combined with 40 ppm nitrite, a *C. botulinum* spore mixture of types A and B strains was inhibited for 60 days at 27°C in comminuted pork (92).

In an evaluation of the interaction of nitrite and sorbate, the relative effectiveness of the combination has been shown to be dependent upon other cure ingredients and product parameters. Employing a liver-veal agar medium at pH 5.8–6.0, the germination rate of *C. botulinum* type E spores decreased to nearly zero with 1.0, 1.5, or 2.0% sorbate; but with the same concentrations at pH 7.0–7.2, germination and outgrowth of abnormally shaped cells occurred (108). When 500 ppm nitrite was added to the higher-pH medium along with sorbate, cell lysis was enhanced. These investigators also found that 500 ppm linoleic acid alone at the higher pH prevented emergence and elongation of spores. Potassium sorbate significantly decreased toxin production by types A and B spores in pork slurries when NaCl was increased or pH and storage temperature were reduced (102). For chicken frankfurters, a sorbate-betalains mixture was found to be as effective as a conventional nitrite system for inhibiting *C. perfringens* growth (128).

Mode of action

It appears that nitrite inhibits *C. botulinum* by interfering with iron-sulfur enzymes such as ferredoxin and thus preventing the synthesis of ATP from

Table 11-2. Effect of nitrite and sorbate on toxin production in bacon inoculated with *C. botulinum* types A and B spores and held up to 60 days at 27°C (114).

Treatment	Percent Toxigenic
Control (no NO ₂ , no sorbate)	90.0
0.26% sorbate, no NaNO ₂	58.8
0.26% sorbate + 40 ppm NaNO ₂	22.0
0.26% sorbate + 80 ppm NaNO ₂	0.0
No sorbate, 120 ppm NaNO ₂	0.4

pyruvate. The first direct finding in this regard was that of Woods et al. (132), who showed that the phosphoroclastic system of *C. sporogenes* is inhibited by nitric oxide, and later that the same occurs in *C. botulinum*, resulting in the accumulation of pyruvic acid in the medium (131).

The phosphoroclastic reaction involves the breakdown of pyruvate with inorganic phosphate and coenzyme A to yield acetyl phosphate. In the presence of ADP, ATP is synthesized from acetyl phosphate with acetate as the other product. In the breakdown of pyruvate, electrons are transferred first to ferredoxin, and from ferredoxin to H^+ to form H_2 in a reaction catalyzed by hydrogenase. Ferredoxin and hydrogenase are iron-sulfur (nonheme) proteins or enzymes (11).

Following the work of Woods and Wood (131), the next most significant finding was that of Reddy et al. (94), who subjected extracts of nitrite-ascorbate-treated *C. botulinum* to electron spin resonance and found that nitric oxide reacted with iron-sulfur complexes to form iron-nitrosyl complexes. The presence of the latter results in the destruction of iron-sulfur enzymes such as ferredoxin.

The resistance of the lactic acid bacteria to nitrite inhibition is well known, but the basis is just now clear: these organisms lack ferredoxin. The clostridia contain both ferredoxin and hydrogenase, which function in electron transport in the anaerobic breakdown of pyruvate to yield ATP, H_2 , and CO_2 . The ferredoxin in clostridia has a molecular weight of 6,000 and contains 8 Fe atoms/mole and 8-labile sulfide atoms/mole.

Although the first definitive experimental finding was reported in 1981 as noted above, earlier work pointed to iron-sulfur enzymes as the probable nitrite targets. Among the first were O'Leary and Solberg (85), who showed that a 91% decrease occurred in the concentration of free —SH groups of soluble cellular compounds of *C. perfringens* inhibited by nitrite. Two years later, Tompkin et al. (125) offered the hypothesis that nitric oxide reacted with iron in the vegetative cells of *C. botulinum*, perhaps the iron in ferredoxin. The inhibition by nitrite of active transport and electron transport was noted by several investigators, and these effects are consistent with nitrite inhibition of nonheme enzymes such as ferredoxin and hydrogenase (105, 133). The enhancement of inhibition in the presence of sequestering agents may be due to the reaction of sequestrants to substrate iron: more nitrite becomes available for nitric oxide production and reaction with microorganisms.

Summary of nitrite effects

The following summary of the overall role and effects of nitrite in cured meats emphasizes the antibotulinal activities.

When added to processed meats such as wieners, bacon, smoked fish, and canned cured meats followed by substerilizing heat treatments, nitrite has definite antibotulinal effects. It also forms desirable product color and enhances flavor in cured meat products. The antibotulinal effect consists of inhibition of vegetative cell growth and the prevention of germination

and growth of spores that survive heat processing or smoking during post-processing storage. Clostridia other than *C. botulinum* are affected in a similar manner. While low initial levels of nitrite are adequate for color and flavor development, considerably higher levels are necessary for the antimicrobial effects.

When nitrite is heated in certain laboratory media, an antibotulinal factor or inhibitor is formed, the exact identity of which is not yet known. The inhibitory factor is the Perigo effect/factor or Perigo inhibitor. It does not form in filter-sterilized media. It develops in canned meats only when nitrite is present during heating. The initial level of nitrite is more important to antibotulinal activity than the residual level. Once formed, the Perigo factor is not affected greatly by pH changes.

Measurable preheating levels of nitrite decrease considerably during heating in meats and during postprocessing storage, more at higher storage temperatures than at lower.

The antibotulinal activity of nitrite is interdependent with pH, salt content, temperature of incubation, and numbers of botulinal spores. Heat-injured spores are more susceptible to inhibition than uninjured. Nitrite is more effective under Eh- than under Eh+ conditions.

Nitrite does not decrease the heat resistance of spores. It is not affected by ascorbate in its antibotulinal actions but does act synergistically with ascorbate in pigment formation.

Lactic acid bacteria are relatively resistant to nitrite (see above).

Endospores remain viable in the presence of the antibotulinal effect and will germinate when transferred to nitrite-free media.

Nitrite has a pK of 3.29 and consequently exists as undissociated nitrous acid at low pH values. The maximum undissociated state and consequent greatest antibacterial activity of nitrous acid are between pH 4.5 and 5.5.

With respect to its depletion or disappearance in ham, Nordin (84) found the rate to be proportional to its concentration and to be exponentially related to both temperature and pH. The depletion rate doubled for every 12.2°C increase in temperature or 0.86 pH unit decrease, and was not affected by heat denaturation of the ham. These relationships did not apply at room temperature unless the product was first heat treated, suggesting that viable organisms aided in its depletion.

It appears that the antibotulinal activity of nitrite is due to its inhibition of nonheme, iron-sulfur enzymes.

NaCl AND SUGARS

These compounds are grouped together because of the similarity in their modes of action in preserving foods. NaCl has been employed as a food preservative since ancient times (see Chapter 1). The early food uses of salt were for the purpose of preserving meats. This use is based upon the fact that at high concentrations, salt exerts a drying effect upon both food

and microorganisms. Nonmarine microorganisms may be thought of as normally possessing a degree of intracellular tonicity equivalent to that produced by about 0.85–0.9% NaCl. When microbial cells are suspended in salt (saline) of this concentration, the suspending menstrum can be said to be isotonic with respect to the cells. Since the amounts of NaCl and water are equal on both sides of the cell membrane, water moves across the cell membranes equally in both directions. When microbial cells are suspended in, say, a 5% saline solution, the concentration of water is greater inside the cells than outside (concentration of H_2O is highest where solute concentration is lowest). It should be recalled that in diffusion, water moves from its area of high concentration to its area of low concentration. In this case, water would pass out of the cells at a greater rate than it would enter. The result to the cell is **plasmolysis**, which results in growth inhibition and possibly death. This is essentially what is achieved when high concentrations of salt are added to fresh meats for the purpose of preservation. Both the microbial cells and those of the meat undergo plasmolysis (shrinkage), resulting in the drying of the meat as well as inhibition or death of microbial cells. To be effective, one must use enough salt to effect **hypertonic** conditions. The higher the concentration, the greater the preservative and drying effects. In the absence of refrigeration, fish and other meats may be effectively preserved by salting. The inhibitory effects of salt are not dependent upon pH as are some other chemical preservatives. Most nonmarine bacteria can be inhibited by 20% or less of NaCl, while some molds generally tolerate higher levels. Organisms that can grow in the presence of and require high concentrations of salt are referred to as **halophiles**, while those that can withstand but not grow in high concentrations are referred to as **halodurics**. The interaction of salt with nitrite and other agents in the inhibition of *C. botulinum* is discussed above under nitrites.

Sugars, such as sucrose, exert their preserving effect in essentially the same manner as salt. One of the main differences is in relative concentrations. It generally requires about six times more sucrose than NaCl to effect the same degree of inhibition. The most common uses of sugars as preserving agents are in the making of fruit preserves, candies, condensed milk, and the like. The shelf-stability of certain pies, cakes, and other such products is due in large part to the preserving effect of high concentrations of sugar, which, like salt, makes water unavailable to microorganisms.

Microorganisms differ in their response to hypertonic concentrations of sugars, with yeasts and molds being less susceptible than bacteria. Some yeasts and molds can grow in the presence of as much as 60% sucrose while most bacteria are inhibited by much lower levels. Organisms that are able to grow in high concentrations of sugars are designated **osmophiles**, while **osmoduric** microorganisms are those that are unable to grow but are able to withstand high levels of sugars. Some osmophilic yeasts such as *Saccharomyces rouxii* can grow in the presence of extremely high concentrations of sugars.

INDIRECT ANTIMICROBIALS

The compounds and products in this section are added to foods primarily for effects other than antimicrobial and are thus multifunctional food additives.

Antioxidants

Although used in foods primarily to prevent the auto-oxidation of lipids, the phenolic antioxidants listed in Table 11-3 have been shown to possess antimicrobial activity against a wide range of microorganisms including some viruses, mycoplasmas, and protozoa. These compounds have been evaluated extensively as nitrite-sparing agents in processed meats and in combination with other inhibitors, and several excellent reviews have been made (10, 37, 65).

Butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and *t*-butylhydroxyquinoline (TBHQ) are inhibitory to gram-positive and gram-negative bacteria as well as to yeasts and molds at concentrations ranging from about 10 to 1,000 ppm depending upon substrate. In general, higher concentrations are required to inhibit in foods than in culture media, especially in high-fat foods. BHA was about fifty times less effective against *Bacillus* spp. in strained chicken than in nutrient broth (110). BHA, BHT, TBHQ, and propyl gallate (PG) were all less effective in ground pork than in culture media (38). While strains of the same bacterial species may show wide variation in sensitivity to either of these antioxidants, it appears that BHA

Table 11-3. Some GRAS indirectly antimicrobial chemicals used in foods.

Compound	Primary use	Most susceptible organisms
Butylated hydroxyanisole (BHA)	Antioxidant	Bacteria, some fungi
Butylated hydroxytoluene (BHT)	Antioxidant	Bacteria, viruses, fungi
<i>t</i> -butylhydroxyquinoline (TBHQ)	Antioxidant	Bacteria, fungi
Propyl gallate (PG)	Antioxidant	Bacteria
Nordihydroguaiaretic acid	Antioxidant	Bacteria
Ethylenediamine tetraacetic acid (EDTA)	Sequestrant/stabilizer	Bacteria
Sodium citrate	Buffer/sequestrant	Bacteria
Lauric acid	Defoaming agent	Gram-positive bacteria
Monolaurin	Emulsifier	Gram-positive bacteria, yeasts
Diacetyl	Flavoring	Gram-negative bacteria, fungi
<i>d</i> - and <i>l</i> -carvone	Flavoring	Fungi, gram-positive bacteria
Phenylacetaldehyde	Flavoring	Fungi, gram-positive bacteria
Menthol	Flavoring	Bacteria, fungi
Vanillin, ethyl vanillin	Flavoring	Fungi
Spices/spice oils	Flavoring	Bacteria, fungi

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and TBHQ are more inhibitory than BHT to bacteria and fungi, while the latter is more viristatic. To prevent growth of *C. botulinum* in a prereduced medium, 50 ppm BHA and 200 ppm BHT were required, while 200 ppm PG were ineffective (99). Employing 16 gram-negative and 8 gram-positive bacteria in culture media, Gailani and Fung (38) found the gram positives to be more susceptible than gram negatives to BHA, BHT, TBHQ, and PG with each being more effective in nutrient agar than in BHT broth. In nutrient agar the relative effectiveness was BHA > PG > TBHQ > BHT, while in BHI, TBHQ > PG > BHA > BHT.

Food-borne pathogens such as *B. cereus*, *V. parahaemolyticus*, salmonellae, and *S. aureus* are effectively inhibited at concentrations < 500 ppm, while some are sensitive to as little as 10 ppm. The pseudomonads, especially *P. aeruginosa*, are among the most resistant bacteria. Three toxin-producing penicillia were inhibited significantly in salami by BHA, TBHQ, and a combination of these two at 100 ppm, while BHT and PG were ineffective (74). Combinations of BHA/sorbate and BHT/monolaurin have been shown to be synergistic against *S. aureus* (10, 21), and BHA/sorbate against *S. typhimurium* (21). BHT/TBHQ has been shown to be synergistic against aflatoxin-producing penicillia (74).

Flavoring agents

Of the many agents used to impart aromas and flavors to foods, some possess definite antimicrobial effects. In general, flavor compounds tend to be more antifungal than antibacterial. The nonlactic, gram-positive bacteria are the most sensitive and the lactic acid bacteria are rather resistant. The essential oils and spices have received the most attention by food microbiologists, while the aroma compounds have been studied more for their use in cosmetics and soaps.

Of twenty-one flavoring compounds examined in one study, about one-half had minimal inhibitory concentrations (MIC) of 1,000 ppm or less against either bacteria or fungi (61). All were pH sensitive, with inhibition increasing as pH and temperature of incubation decreased. Some of these compounds are noted in Table 11-3.

One of the most effective flavoring agents is diacetyl, which imparts the aroma of butter (58). It is somewhat unique in being more effective against gram-negative bacteria and fungi than against gram-positive bacteria. In plate count agar at pH 6.0 and incubation at 30°C, all but one of twenty-five gram-negative bacteria and fifteen of sixteen yeasts and molds were inhibited by 300 ppm (59). At pH 6.0 and incubation at 5°C in nutrient broth, < 10 ppm inhibited *P. fluorescens*, *P. geniculata*, and *S. faecalis*, while under the same conditions except with incubation at 30°C, about 240 ppm were required to inhibit these and other organisms (61). It appears that diacetyl antagonizes arginine utilization by reacting with arginine-binding proteins of gram-negative bacteria. The greater resistance of gram-positive bacteria appears to be due to their lack of similar periplasmic binding

proteins and their possession of larger amino acid pools. Another flavor compound that imparts the aroma of butter is 2,3-pentanedione, and it has been found to be inhibitory to a limited number of gram-positive bacteria and fungi at 500 ppm or less (61).

The agent *l*-carvone imparts spearmintlike and the agent *d*-carvone imparts carawaylike aromas, and both are antimicrobial with the *l*-isomer being more effective than the *d*-isomer, while both are more effective against fungi than bacteria at 1,000 ppm or less (61). Phenylacetaldehyde imparts a hyacinthlike aroma, and has been shown to be inhibitory to *S. aureus* at 100 ppm and *Candida albicans* at 500 ppm (61, 83). Menthol, which imparts a peppermintlike aroma, was found to inhibit *S. aureus* at 32 ppm, and *E. coli* and *C. albicans* at 500 ppm (61, 83). Vanillin and ethyl vanillin are inhibitory, especially to fungi at levels < 1,000 ppm.

Spices and essential oils

While used primarily as flavoring and seasoning agents in foods, many spices possess significant antimicrobial activity. In all instances, antimicrobial activity is due to specific chemicals or essential oils, some of which are noted in Chapter 3. The search for nitrite-sparing agents generated new interest in spices and spice extracts in the late 1970s (much of this work has been reviewed by Shelef, 109).

It would be difficult to predict what antimicrobial effects if any are derived from spices as they are used in foods, for the quantities employed differ widely depending upon taste and the relative effectiveness varies depending upon product composition. Because of the varying concentrations of the antimicrobial constituents in different spices, and because many studies have been conducted employing them on a dry weight basis, it is difficult to ascertain the MIC of given spices against specific organisms. Another reason for conflicting results by different investigators is the assay method employed. In general, higher MIC values are obtained when highly volatile compounds are evaluated on the surface of plating media than when they are tested in pour plates or broth. When eugenol was evaluated by surface plating onto PCA at pH 6, only nine of fourteen gram-negative and twelve of twenty gram-positive bacteria (including eight lactics) were inhibited by 493 ppm, while in nutrient broth at the same pH, MICs of 32 and 63 were obtained for *Torulopsis candida* and *Aspergillus niger*, and *S. aureus* and *E. coli*, respectively (61). It has been noted that spice extracts are less inhibitory in media than spices, and this is probably due to a slower release of volatiles by the latter (111). In spite of the difficulties of comparing results from study to study, the antimicrobial activity of spices is unquestioned and a large number of investigators have shown the effectiveness of at least twenty different spices or their extracts against most food-poisoning organisms including mycotoxigenic fungi (109).

In general, spices are less effective in foods than in culture media, and gram-positive bacteria are more sensitive than gram negatives, with the

lactic acid bacteria being the most resistant among gram positives (134). While results concerning them are debatable, the fungi appear to be in general more sensitive than gram-negative bacteria. Some gram negatives, however, are highly sensitive. Antimicrobial substances vary in content from the allicin of garlic (with a range of 0.3–0.5%) to eugenol in cloves (16–18%) (109). When whole spices are employed, MIC values range from 1–5% for sensitive organisms. Sage and rosemary are among the most antimicrobial as reported by various researchers, and it has been reported that 0.3% in culture media inhibited twenty-one of twenty-four gram-positive bacteria and were more effective than allspice (111).

With respect to specific inhibitory levels of extracts and essential oils, Huhtanen (53) made ethanol extracts of thirty-three spices, tested them in broth against *C. botulinum*, and found that achiote and mace extracts produced an MIC of 31 ppm and were the most effective of the thirty-three. Next most effective were nutmeg, bay leaf, and white and black peppers with MICs of 125 ppm. Employing the essential oils of oregano, thyme, and sassafras, Beuchat (4) found that 100 ppm were lethal to *V. parahaemolyticus* in broth. Growth and aflatoxin production by *A. parasiticus* in broth were inhibited by 200–300 ppm of cinnamon and clove oils, by 150 ppm cinnamic aldehyde, and by 125 ppm eugenol (12).

The mechanisms by which spices inhibit microorganisms are unclear and may be presumed to be different for unrelated groups of spices. That the mechanism for oregano, rosemary, sage, and thyme may be similar is suggested by the finding that resistance development by some lactic acid bacteria to one was accompanied by resistance to the other three (134).

Medium-chain fatty acids and esters

Acetic, propionic, and sorbic acids are short-chain fatty acids used primarily as preservatives. Medium-chain fatty acids, however, are employed primarily as surface-active or emulsifying agents. The antimicrobial activity of the medium-chain fatty acids is best known from soaps, which are salts of fatty acids. Those most commonly employed are composed of twelve to sixteen carbons. For saturated fatty acids, the most antimicrobial chain length is C_{12} ; for monounsaturated (containing 1 double bond) $C_{16:1}$; and for polyunsaturated (containing more than one double bond) $C_{18:2}$ is the most antimicrobial (66). In general, fatty acids are effective primarily against gram-positive bacteria and yeasts. While the C_{12} to C_{16} chain lengths are the most active against bacteria, the C_{10} to C_{12} are most active against yeasts (66). Fatty acids and esters and the structure-function relationships among them have been reviewed and discussed by Kabara (65, 66). Saturated aliphatic acids effective against *C. botulinum* have been evaluated by Dymicky and Trenchard (32).

The monoesters of glycerol and the diesters of sucrose have been found to be more antimicrobial than the corresponding free fatty acids, and to compare favorably with sorbic acid and the parabens as antimicrobials (65).

Monolaurin is the most effective of the glycerol monoesters, while sucrose dicaprylate is the most effective of the sucrose diesters. Monolaurin (lauricidin) has been evaluated by a large number of investigators and found to be inhibitory to a variety of gram-positive bacteria and some yeasts at 5–100 ppm (10, 65). Unlike the short-chain fatty acids, which are most effective at low pH, monolaurin is effective over the range 5.0 to 8.0 (67).

Because the fatty acids and esters have a narrow range of effectiveness and GRAS substances such as EDTA, citrate, and phenolic antioxidants also have limitations as antimicrobial agents when used alone, Karara (65, 66) has stressed the "preservative system" approach to the control of microorganisms in foods by using combinations of chemicals to fit given food systems and preservation needs. By this approach, a preservative system might consist of three compounds—monolaurin/EDTA/BHA, for example. While EDTA possesses little antimicrobial activity by itself, it renders gram-negative bacteria more susceptible by rupturing the outer membrane and thus potentiating the effect of fatty acids or fatty acid esters. An antioxidant such as BHA would exert effects against bacteria and molds and serve as an antioxidant at the same time. By use of such a system, the development of resistant strains could be minimized and the pH of a food could become less important relative to the effectiveness of the inhibitory system.

ACETIC AND LACTIC ACIDS

These two organic acids are among the most widely employed as preservatives. In most instances, their origin in the subject foods is due to their production within the food by lactic acid bacteria. Products such as pickles, sauerkraut, and fermented dairy products, among others, are created by the fermentative activities of various lactic acid bacteria, which produce acetic, lactic, and other acids (see Chapter 16 for fermented foods, and the review by Doores, 28, for further information).

The antimicrobial effect of organic acids such as propionic and lactic is due both to the depression of pH below the growth range and metabolic inhibition by the undissociated acid molecules. In determining the quantity of organic acids in foods, titratable acidity is of more value than pH alone, since the latter is a measure of hydrogen ion concentration and organic acids do not ionize completely. In measuring titratable acidity, the amount of acid capable of reacting with a known amount of base is determined. The titratable acidity of products such as sauerkraut is a better indicator of the amount of acidity present than pH.

ANTIBIOTICS

While no antibiotic is legally permissible as a food additive in the United States at the present time, two are approved for food use in many other

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countries (nisin and natamycin), and three others (tetracyclines, subtilin, and tylosin) have been studied and found effective for various food applications. The early history, efficacy, and applications of most were reviewed in 1966 (78), and all have been reviewed and discussed more recently (60). Detailed reviews on nisin have been provided by Hurst (54, 55) and Lipinska (75).

Three antibiotics have been investigated extensively as heat adjuncts for canned foods (subtilin, tylosin, and nisin). Nisin, however, is used most widely in cheeses. Chlortetracycline and oxytetracycline were widely studied for their application to fresh foods while natamycin is employed as a food fungistat.

While in general the use of chemical preservatives in foods is not popular among many consumers, the idea of employing antibiotics is even less popular. Some risks may be anticipated from the use of any food additive, but the risks should not outweigh the benefits overall. The general view in the United States at the present time is that the benefits to be gained by using antibiotics in foods do not outweigh the risks, some of which are known and some of which are presumed. Some fifteen considerations on the use of antibiotics as food preservatives were noted by Ingram et al. (56), and several of the key ones are summarized below:

1. The antibiotic agent should kill, not inhibit the flora, and should ideally decompose into innocuous products, or be destroyed on cooking for products that require cooking.
2. The antibiotic should not be inactivated by food components or products of microbial metabolism.
3. The antibiotic should not readily stimulate the appearance of resistant strains.
4. The antibiotic should not be used in foods if used therapeutically or as an animal feed additive.

It may be noted from the summary comparison in Table 11-4 that the tetracyclines are used both clinically and as feed additives while tylosin is used in animal feeds and only in the treatment of some poultry diseases. Neither nisin nor subtilin is used medically or in animal feeds, and while nisin is used in many countries, subtilin is not. The structural similarities of these two antibiotics may be noted from Fig. 11-2.

Nisin

This is a polypeptide antibiotic structurally related to subtilin, but unlike subtilin it does not contain tryptophane residues (Fig. 11-2). While the C-terminal amino acids are similar, the N-terminals are not. The first food use of nisin was by Hirsch et al. (51) to prevent the spoilage of Swiss cheese by *Clostridium butyricum*. It is clearly the most widely used antibiotic for food preservation, with around thirty-nine countries permitting its use

in foods to varying degrees (for a list of countries, see Hurst, 54). It is not permitted in foods in the United States and Canada. Among some of its desirable properties as a food preservative are the following: (1) it is nontoxic, (2) it is produced naturally by *Streptococcus lactis* strains, (3) it is heat stable and has excellent storage stability, (4) it is destroyed by digestive enzymes, (5) it does not contribute to off-flavors or off-odors, and (6) it has a narrow spectrum of antimicrobial activity. The compound is effective against gram-positive bacteria, primarily sporeformers, and ineffective against fungi and gram-negative bacteria. *Enterococcus (Streptococcus) faecalis* is one of the most resistant gram positives.

A large amount of research has been carried out with nisin as a heat-adjunct in canned foods, or as an inhibitor of heat-shocked spores of *Bacillus*

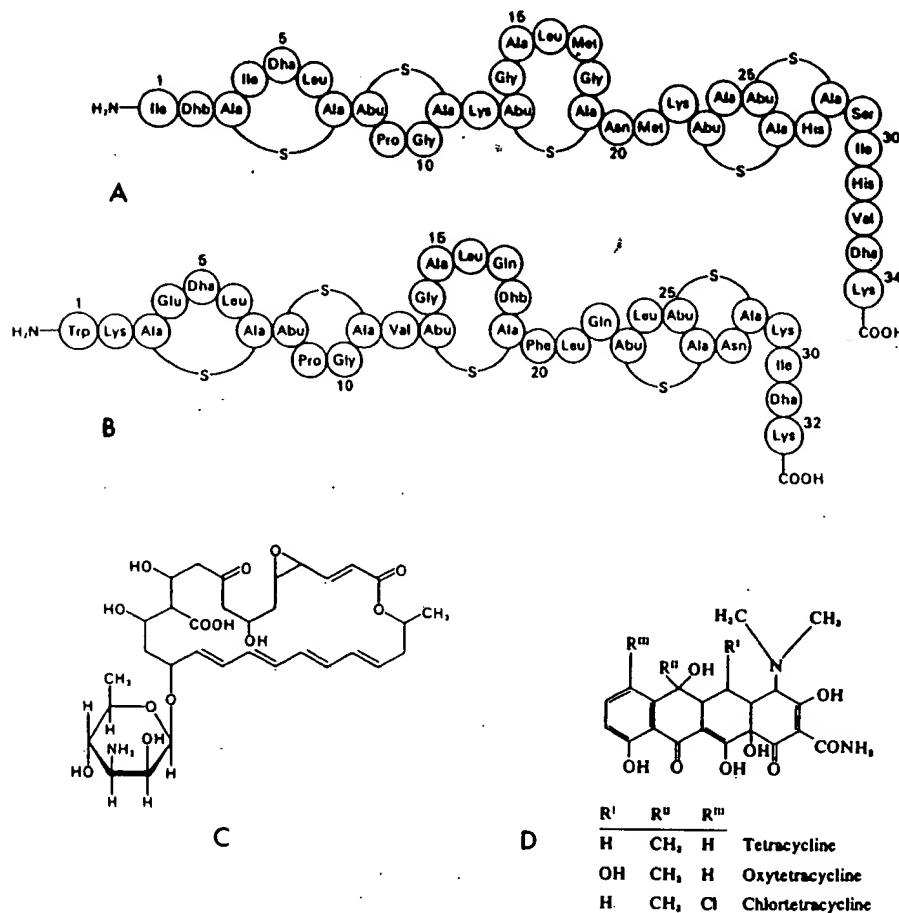


Fig. 11-2. Structural formulae of nisin (A), subtilin (B), natamycin (C), and the tetracyclines (D).

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and *Clostridium* strains, and the MIC for preventing outgrowth of germinating spores ranges widely from 3 to > 5,000 IU/ml or < 1 to > 125 ppm (1 μ g of pure nisin is about 40 IU or RU—Reading unit) (54). Depending upon the country and the particular food product, typical usable levels are in the range of about 2.5 to 100 ppm, although some countries do not impose concentration limits.

A conventional heat process for low-acid canned foods requires an F_0 treatment of 6–8 (see Chapter 14) to inactivate the endospores of both *C. botulinum* and spoilage organisms. By adding nisin the heat process can be reduced to an F_0 of 3 (to inactivate *C. botulinum* spores) resulting in increased product quality of low-acid canned foods. While the low-heat treatment will not destroy the endospores of spoilage organisms, nisin prevents their germination by acting early in the endospore germination cycle (Fig. 11-1). In addition to its use in certain canned foods, nisin is most often employed in dairy products—processed cheeses, condensed milk, pasteurized milk, and so on. Some countries permit its use in processed tomato products and canned fruits and vegetables (54). It is most stable in acidic foods.

Because of the effectiveness of nisin in preventing the outgrowth of germinating endospores of *C. botulinum* and the search to find safe substances that might replace nitrites in processed meats, this antibiotic has been studied as a possible replacement for nitrite. While some studies showed encouraging results employing *C. sporogenes* and other nonpathogenic organisms, a recent study employing *C. botulinum* types A and B spores in pork slurries indicated the inability of nisin at concentrations up to 550 ppm in combination with 60 ppm nitrite to inhibit spore outgrowth (93). Employed in culture media without added nitrite, the quantity of nisin required for 50% inhibition of *C. botulinum* type E spores was 1–2 ppm; 10–20 ppm for type B; and 20–40 ppm for type A (107). The latter authors found that higher levels were required for inhibition in cooked meat medium than in TPYG medium and suggested that nisin was approximately equivalent to nitrite in preventing the outgrowth of *C. botulinum* spores.

With respect to mode of action, nisin and subtilin may be presumed to act similarly since they are both polypeptide antibiotics with highly similar structures. They act at the same site on germinating endospores (Fig. 11-1). Some of the polypeptide antibiotics typically attack cell membranes and act possibly as surfactants or emulsifying agents on membrane lipids. These agents may be presumed to inhibit gram-positive bacteria by inhibiting cell wall murein synthesis since bacitracin (another polypeptide antibiotic that also inhibits gram-positive bacteria) is known to inhibit murein synthesis (47). That nisin affects murein synthesis has been shown by Reisinger et al. (95), and this finding is not inconsistent with its lack of toxicity for man. A similar lack of toxicity for subtilin may be presumed.

Nalamycin

This antibiotic (also known as pimarin, tennecetin, and myprozine) is a polyene that is quite effective against yeasts and molds but not bacteria.

Natamycin is the international nonproprietary name since it was isolated from *Streptomyces natalensis*. Its structural formula is presented in Fig. 11-2.

In granting the acceptance of natamycin as a food preservative, the joint FAO/WHO Expert Committee (35) took the following into consideration: (1) it does not affect bacteria, (2) it stimulates an unusually low level of resistance among fungi, (3) it is rarely involved in cross-resistance among other antifungal polyenes, and (4) DNA transfer between fungi does not occur to the extent that it does with some bacteria. Also, from Table 11-4 it may be noted that its use is limited as a clinical agent, and it is not used as a feed additive. Natamycin has been shown by numerous investigators to be very effective against both yeasts and molds, and many of these reports have been summarized (60).

The relative effectiveness of natamycin was compared to sorbic acid and four other antifungal antibiotics by Klis et al. (69) for the inhibition of sixteen different fungi (mostly molds), and while from 100 to 1,000 ppm sorbic acid were required for inhibition, from 1 to 25 ppm natamycin were effective against the same strains in the same media. To control fungi on strawberries and raspberries, natamycin was compared with rimocidin and nystatin, and it along with rimocidin was effective at levels of 10–20 ppm, while 50 ppm nystatin were required for effectiveness (1). In controlling fungi on salami, the spraying of fresh salami with a 0.25% solution was found to be effective by one group of investigators (50), but another researcher was unsuccessful in his attempts to prevent surface-mold growth on Italian dry sausages when they were dipped in a 2,000-ppm solution (53). Natamycin

Table 11-4. Summary comparison of some properties of the antibiotics discussed in this chapter (60).

Property	Tetracyclines	Subtilin	Tylosin	Nisin	Natamycin
Widely used in foods	No	No	No	Yes	Yes
First food use	1950	1950	1961	1951	1956
Chemical nature	Tetracycline	Poly-peptide	Macro-lide	Poly-peptide	Polyene
Used as heat adjunct	No	Yes	Yes	Yes	No
Heat stability	Sensitive	Stable	Stable	Stable	Stable
Microbial spectrum	G ⁺ , G ⁻	G ⁺	G ⁺	G ⁺	Fungi
Used medically	Yes	No	Yes ^a	No	Yes ^b
Used in feeds	Yes	No	Yes	No	No

^a In treating poultry diseases.

^b Limited.

spray ($2 \times 1,000$ ppm) was as good as or slightly better than 2.5% potassium sorbate.

Natamycin appears to act in the same manner as other polyene antibiotics—by binding to membrane sterols and inducing distortion of selective membrane permeability (45). Since bacteria do not possess membrane sterols, their lack of sensitivity to this agent is thus explained. Mycoplasmae, however, do have membrane sterols, but whether this antibiotic is effective against this group is unclear.

Tetracyclines

Chlortetracycline (CTC) and oxytetracycline (OTC) were approved by the FDA in 1955 and 1956, respectively, at a level of 7 ppm to control bacterial spoilage in uncooked refrigerated poultry, but these approvals were subsequently rescinded. The efficacy of this group of antibiotics in extending the shelf life of refrigerated foods was first established by Tarr and associates in Canada working with fish (120). Subsequent research by a large number of workers in many countries established the effectiveness of CTC and OTC in delaying bacterial spoilage of not only fish and seafoods but poultry, red meats, vegetables, raw milk, and other foods (for a review of food applications, see 60, 78). CTC is generally more effective than OTC. The surface treatment of refrigerated meats with 7–10 ppm typically results in shelf-life extensions of at least 3–5 days and a shift in ultimate spoilage flora from gram-negative bacteria to yeasts and molds. When CTC is combined with sorbate to delay spoilage of fish, the combination has been shown to be effective for up to 14 days. Rockfish fillets dipped in a solution of 5 ppm CTC and 1% sorbate had significantly lower APCs after vacuum-package storage at 2°C after 14 days than controls (81).

The tetracyclines are both heat sensitive and storage labile in foods, and these factors were important in their initial acceptance for food use. As may be noted from Table 11-4, they are used to treat diseases in man and animals and are used also in feed supplements. The risks associated with their use as food preservatives in developed countries seem clearly to outweigh the benefits.

Subtilin

This antibiotic was discovered and developed by scientists at the Western Regional Laboratory of the USDA, and its properties were described by Dimick et al. (27). As noted above, it is structurally similar to nisin (Fig. 11-2) even though it is produced by some strains of *B. subtilis*. Like nisin, it is effective against gram-positive bacteria, is stable to acid, and possesses enough heat resistance to withstand destruction at 121°C for 30 to 60 min. Subtilin is effective in canned foods at levels of 5 to 20 ppm in preventing the outgrowth of germinating endospores, and its site of action is the same as for nisin (Fig. 11-1). Like nisin, it is used neither in the treatment of

human or animal infections nor as a feed additive. This antibiotic may be just as effective as nisin even though it has received little attention since the late 1950s. Its mode of action is discussed above along with that of nisin, and its development and evaluation have been reviewed (60).

Tylosin

This antibiotic is a nonpolyene macrolide as are the clinically useful antibiotics erythromycin, oleandomycin, and others. It is more inhibitory than nisin or subtilin. Denny et al. (23) were apparently the first to study its possible use in canned foods. When 1 ppm was added to cream-style corn containing flat-sour spores and given a "botulinal" cook, no spoilage of product occurred after 30 days with incubation at 54°C (22). Similar findings were made by others in the 1960s, and these have been summarized (60).

Unlike nisin, subtilin, and natamycin, tylosin is used in animal feeds and also to treat some diseases of poultry. As a macrolide, it is most effective against gram-positive bacteria. It inhibits protein synthesis by associating with the 50S ribosomal subunit, and shows at least partial cross-resistance with erythromycin.

ANTIFUNGAL AGENTS FOR FRUITS

Listed in Table 11-5 are some compounds applied to fruits after harvest to control fungi, primarily molds. Benomyl is applied uniformly over the entire surface of fruits, examples of which are noted in the table. It is applied at concentrations of 0.5–1.0 g/liter. It can penetrate the surface of some vegetables, and is used world-wide to control crown rot and anthracnose of bananas, and stem-end rots of citrus fruits. It is more effective than thi-

Table 11-5. Some chemical agents employed to control fungal spoilage of fresh fruits (33).

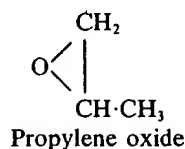
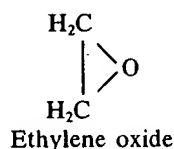
<i>Compound</i>	<i>Fruits</i>
Thiabendazole	Apples, pears, citrus fruits, pineapples
Benomyl	Apples, pears, bananas, citrus fruits, mangoes, papayas, peaches, cherries, pineapples
Biphenyl	Citrus fruits
SO ₂ fumigation	Grapes
Sodium- α -phenylphenate	Apples, pears, citrus fruits, pineapples

bendazole and penetrates with greater ease. Both benomyl and thiabendazole are effective in controlling dry rot caused by *Fusarium* spp. To prevent the spread of *Botrytis* from grape to grape, SO_2 is employed for long-term storage. It is applied shortly after harvest and about once a week thereafter. A typical initial treatment consists of a 20-min application of a 1% preparation, and about 0.25% in subsequent treatments (the use of SO_2 in other foods is discussed above).

Biphenyl is used to control the decay of citrus fruits by penicillia for long-distance shipments and is generally impregnated into fruit wraps or sheets between fruit layers.

ETHYLENE AND PROPYLENE OXIDES

Ethylene and propylene oxides along with ethyl and methyl formate (HCOOC_2H_5 and HCOOCH_3 , respectively) are treated together in this section because of their similar actions. The structures of the oxide compounds are as follows:



The oxides exist as gases and are employed as fumigants in the food industry. The oxides are applied to dried fruits, nuts, spices, and so forth, primarily as antifungal compounds.

Ethylene oxide is an alkylating agent (91) and its antimicrobial activity is presumed to be related to this action in the following manner. In the presence of labile H atoms, the unstable three-membered ring of ethylene oxide splits. The H atom attaches itself to the oxygen, forming a hydroxyl ethyl radical, $\text{CH}_2\text{CH}_2\text{OH}$, which in turn attaches itself to the position in the organic molecule left vacant by the H atom. As a result, the hydroxyl ethyl group blocks reactive groups within microbial proteins, thus resulting in inhibition. Among the groups capable of supplying a labile H atom are the following: $-\text{COOH}$, $-\text{NH}_2$, $-\text{SH}$, and $-\text{OH}$. Ethylene oxide appears to affect endospores of *C. botulinum* by alkylation of guanine and adenine components of spore DNA (80, 130).

Ethylene oxide is used as a gaseous sterilant for flexible and semirigid containers for packaging aseptically processed foods. All of the gas dissipates from the containers following their removal from treatment chambers. With respect to its action on microorganisms, it is not much more effective against vegetative cells than it is against endospores, as can be seen from the D values given in Table 11-6.

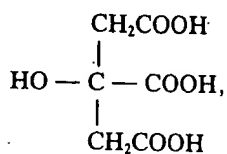
Table 11-6. D values for four chemical sterilants of some food-borne microorganisms.

Organism	D ^a	Conc.	Temp. ^b	Condition	Reference
<i>Hydrogen peroxide</i>					
<i>C. botulinum</i> 169B	0.03	35%	88		121
<i>B. coagulans</i>	1.8	26%	25		122
<i>B. stearothermophilus</i>	1.5	26%	25		122
<i>B. subtilis</i> ATCC 95244	1.5	20%	25		116
<i>B. subtilis</i> A	7.3	26%	25		121
<i>Ethylene oxide</i>					
<i>C. botulinum</i> 62A	11.5	700 mg/L	40	47% R.H.	106
<i>C. botulinum</i> 62A	7.4	700 mg/L	40	23% R.H.	130
<i>C. sporogenes</i> ATCC 7955	3.25	500 mg/L	54.4	40% R.H.	68
<i>B. coagulans</i>	7.0	700 mg/L	40	33% R.H.	7
<i>B. coagulans</i>	3.07	700 mg/L	60	33% R.H.	7
<i>B. stearothermophilus</i> ATCC 7953	2.63	500 mg/L	54.4	40% R.H.	68
<i>L. brevis</i>	5.88	700 mg/L	30	33% R.H.	7
<i>M. radiodurans</i>	3.00	500 mg/L	54.4	40% R.H.	68
<i>Sodium hypochlorite</i>					
<i>A. niger</i> conidiospores	0.61	20 ppm ^c	20	pH 3.0	15
<i>A. niger</i> conidiospores	1.04	20 ppm ^c	20	pH 5.0	15
<i>A. niger</i> conidiospores	1.31	20 ppm ^c	20	pH 7.0	15
<i>Iodine (1/2 I₂)</i>					
<i>A. niger</i> conidiospores	0.86	20 ppm ^c	20	pH 3.0	15
<i>A. niger</i> conidiospores	1.15	20 ppm ^c	20	pH 5.0	15
<i>A. niger</i> conidiospores	2.04	20 ppm ^c	20	pH 7.0	15

^a In minutes;^b °C;^c As Cl.

MISCELLANEOUS CHEMICAL PRESERVATIVES

Sodium diacetate ($\text{CH}_3\text{COONa} \cdot \text{CH}_3\text{COOH} \cdot x\text{H}_2\text{O}$), a derivative of acetic acid, is used in bread and cakes to prevent moldiness. Organic acids such as citric,



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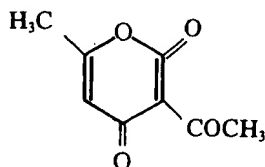
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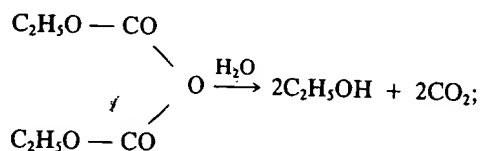
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exert a preserving effect on foods such as soft drinks. **Hydrogen peroxide** (H_2O_2) has received limited use as a food preservative. In combination with heat, it has been used in milk pasteurization and sugar processing, but its widest use is as a sterilant for food-contact surfaces of olefin polymers and polyethylene in aseptic packaging systems (see Chapter 14). The D values of some food-borne microorganisms are presented in Table 11-6. **Ethanol** ($\text{C}_2\text{H}_5\text{OH}$) is present in flavoring extracts and effects preservation by virtue of its desiccant and denaturant properties. **Dehydroacetic acid**,

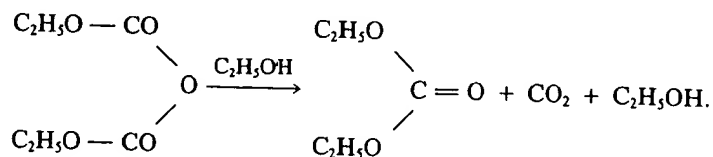


is used to preserve squash. **Diethylpyrocarbonate** has been used in bottled wines and soft drinks as a yeast inhibitor. It decomposes to form ethanol and CO_2 by either hydrolysis or alcoholysis (39):

Hydrolysis (reaction with water):



Alcoholysis (reaction with ethyl alcohol):



Saccharomyces cerevisiae and conidia of *Aspergillus niger* and *Byssoschlamys fulva* have been shown to be destroyed by this compound during the first $\frac{1}{2}$ h of exposure, while the ascospores of *B. fulva* required 4 to 6 h for maximal destruction (115). Cidal concentrations for yeasts range from about 20 to 1,000 ppm depending upon species or strain. *Lactobacillus plantarum* and *Leuconostoc mesenteroides* required 24 h or longer for destruction. Sporeforming bacteria are quite resistant to this compound. Sometimes urethane is formed when this compound is used and because it is a carcinogen, the use of diethylpyrocarbonate is no longer permissible in the United States.

Wood smoke imparts certain chemicals to smoked products that enable these products to resist microbial spoilage. One of the most important is formaldehyde (CH_2O), which has been known for many years to possess antimicrobial properties. This compound acts as a protein denaturant by virtue of its reaction with amino groups. Also in wood smoke are aliphatic acids, alcohols, ketones, phenols, higher aldehydes, tar, methanol, cresols, and other compounds (30), all of which may contribute to the antibacterial actions of meat smoking. Since a certain amount of heat is necessary to produce smoke, part of the shelf-stability of smoked products is due to heat destruction of surface organisms as well as to the drying that occurs. A study of the antibacterial activity of liquid smoke by Handford and Gibbs (46) revealed that little activity occurred at concentrations of smoke that produced acceptable smoked flavor. Employing an agar medium containing 1:1 dilution of smoked water, these investigators found that micrococci and staphylococci were slightly more inhibited than the lactic acid bacteria. The overall combined effect of smoking and vacuum packaging results in a reduction of numbers of catalase-positive bacteria on the smoked product, while the catalase-negative lactic acid bacteria are better able to withstand the low Eh conditions of vacuum-packaged products.

The lactoperoxidase system is an inhibitory system that occurs naturally in bovine milk. It consists of three components: lactoperoxidase, thiocyanate, and H_2O_2 . All three components are required for antimicrobial effects, and the gram-negative psychrotrophs such as the pseudomonads are quite sensitive. The quantity of lactoperoxidase needed is 0.5–1.0 ppm, while bovine milk normally contains about 30 ppm (5). While both thiocyanate and H_2O_2 occur normally in milk, the quantities vary. For H_2O_2 about 100 U/ml are required in the inhibitory system, while only 1–2 U/ml normally occurs in milk. An effective level of thiocyanate is around 0.25 mM, while in milk the quantity varies between 0.02–0.25 mM (5).

When the lactoperoxidase system in raw milk was activated by adding thiocyanate to 0.25 mM along with an equimolar amount of H_2O_2 , the shelf life was extended to 5 days compared to 48 h for controls (5). The system was more effective at 30 than at 4°C. The bactericidal effect increases with acidity, and the cytoplasmic membrane appears to be the cell target. In addition to the direct addition of H_2O_2 , an exogenous source can be provided by the addition of glucose and glucose oxidase. To avoid the direct addition of glucose oxidase, this enzyme has been immobilized on glass beads so that glucose is generated only in the amounts needed by the use of immobilized β -galactosidase (6). The lactoperoxidase system can be used to preserve raw milk in countries where refrigeration is uncommon. The addition of about 12 ppm of SCN^- and 8 ppm of H_2O_2 should be harmless to the consumer (97). The system has been described in detail by Law and Reiter (72), Law and Mabbitt (71), and Reiter (96); and reviewed by Reiter and Harnulv (97).

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	: John H. Lee et al.	
Appln. No.	: 09/392,243	
Filed	: September 9, 1999	Group Art Unit: 1651
Title	: PROCESSES FOR MAKING PROTEIN HYDROLYSATES FROM ANIMAL PEPTONE AND FOR PRESERVING MUCOSA	Examiner: F. Prats
Docket No.	: LL11.12-0073	

EXHIBIT E OF APPENDIX B IN BRIEF FOR APPELLANT

Merriam-Webster Dictionary Definition of OXIDIZE
obtained from www.m-w.com (12-18-02)



- Home ► Help
- Word of the Day
- Word Games
- Word for the Wise
- Books and CDs
- Company Info
- Customer Service
- Network Options
- Language Zone
- The Lighter Side
- Site Map



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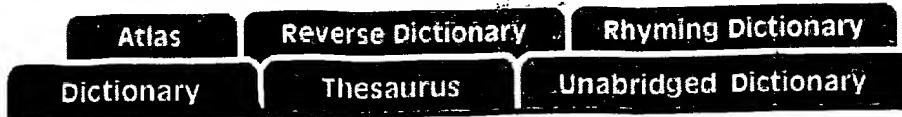
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Collegiate Dictionary
& Thesaurus CD-ROM
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Merriam-Webster DICTIONARY

Merriam-Webster



One entry found for **oxidize**.

Main Entry: **ox·i·dize** ◀▶

Pronunciation: 'äk-s&- "dIz

Function: *verb*

Inflected Form(s): **-dized; -diz-ing**

Date: 1806

transitive senses

1 : to combine with oxygen

2 : to dehydrogenate especially by the action of oxygen

3 : to change (a compound) by increasing the proportion of the electronegative part or change (an element or ion) from a lower to a higher positive valence : remove one or more electrons from (an atom, ion, or molecule)

intransitive senses : to become **oxidized**

- **ox·i·diz·able** ◀▶ / "äk-s&- 'dI-z&-b&l/ *adjective*

Get the **Top 10 Most Popular Sites for "oxidize"**

For **More Information on "oxidize"** go to **Britannica.com**

Find **Photos, Magazines and Newspaper Articles about "oxidize"** at eLibrary. Free registration required.

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In fact, there's a new word waiting in your e-mail in box every morning when you subscribe to the Word of the Day.

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Listen to broadcasts or read transcripts of previous Word for the Wise programs on public radio.

Pronunciation Symbols

\ə\ as a and u in abut

\ē\ as e in kitten

\ə\ as ur/er in further.

\ə\ as a in ash

\ā\ as a in ace

\ā\ as o in mop

\ə\ as ou in out

\e\ as e in bet

\ē\ as ea in easy

\g\ as g in go

\i\ as i in hit

\ī\ as i in ice

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\th\ as th in thin

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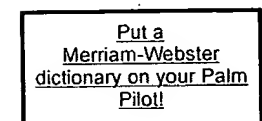
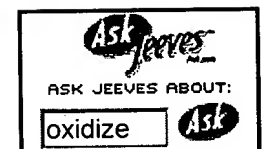
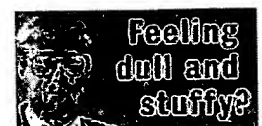
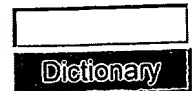
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APPENDIX C ****
TABLE OF CASES

<i>Ex parte Dotter</i> , 12 U.S.P.Q. 382 (Bd. App. 1931).	
<i>In re Driscoll</i> , 562 F.2d 1245, 195 USPQ 434 (C.C.P.A. 1977).	
<i>In re Fine</i> , 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).	
<i>In re Jones</i> , 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992).	
<i>In re Linter</i> , 458 F.2d 1013, 173 U.S.P.Q. 560 (C.C.P.A. 1972).	
<i>In re Mills</i> , 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).	
<i>In re Rijckaert</i> , 28 U.S.P.Q.2d 1955 (Fed. Cir. 1993).	
<i>W.L. Gore & Associates, Inc. v. Garlock, Inc.</i> , 220 U.S.P.Q. 303 (Fed. Cir. 1983).	
<i>Buell v. Beckstrom</i> , 22 U.S.P.Q.2d 1128, 1133 (P.T.O. Bd. Pat. App. & Int'f. 1992)	
<i>In re Miller</i> , 169 U.S.P.Q. 597, 599 (C.C.P.A. 1971).	
<i>In re Skoll</i> , 187 U.S.P.Q. 481, 482 (C.C.P.A. 1975)	
<i>In re Mercier</i> , 185 U.S.P.Q. 774, 780 (C.C.P.A. 1975)	

said patents. The securing of the lamp to the windshield frame, the length of the tube extending from the handle to the lamp, and the means whereby the handle was operated—all presented matters of choice of means for the mechanic rather than an original combination of elements which evidenced the quality of invention.

Taking claim 6 specifically, we find that Rice made use of a windshield. Cousino does not describe any particular form of spotlight mounting device to be attached to the frame. Rice and Ramsey both had their mounting device include a guide projecting laterally therefrom, a spotlight carrying bracket on the outer end of said guide, and a handle transversely extending rearwardly on the inner end of said guide, said handle connected through the guide to rock the spotlight bracket on said guide as a horizontal axis, and said handle rotatable to oscillate the spotlight bracket on an axis intersecting the axis of the guide. In view of Ramsey and Rice, we conclude that claim 6 was anticipated, and, if not fully anticipated, they clearly pointed the way. The Cousino combination described in claim 6, therefore, did not spell patentable novelty.

Claim 5, however, while not specifically limited to use on a closed car, contained an element—"a friction clamp anchored adjacent said windshield and embracing said sleeve"—which is not found in claim 6.

Unity asserts that its patent does not infringe this claim because of the absence of any friction clamp so anchored. We are inclined to think that its device is the equivalent of this friction clamp, but on the other hand the adoption of such a friction clamp was so obvious a necessity and so simple a means as to necessitate its being called a mechanic's adoption of a well-known method to secure the desired result rather than an inventor's conception.

Differences between the Rice lamp and the Cousino lamp are due largely to their use on different kinds of automobiles. When the Cousino lamp was placed on the market, most cars were closed. When the Rice lamp was pat-

ented, open cars were made almost exclusively. This difference accounts for the size of the tube leading from the lamp to the handle in the Cousino lamp. Obviously, this was a matter of choice on the part of the mechanic. For if a tube is to pass through a small frame like a windshield frame it must be small. Its size plays no part in its function. Moreover, neither claim mentions the size of the tube which passes through the windshield frame.

Nor can we attribute invention to the difference between the adjusting means—one called rocking and the other, a rotating movement of the pitman rod. In view of the prior art and in view of the well known and commonly adopted means of securing either movement a mechanic was free to choose either.

What has been said about extensive use applies to the Cousino patent as well as to the Ramsey patent. The change from open to closed cars made it necessary for the manufacturer to provide lamps with rods which passed through the windshield frame. The enormous increase in the number of such cars, coupled with the fact that the Lorraine lamp was well made and well served its purpose and satisfied the customers, accounted for its large sales rather than any unusual novelty in its structure. We conclude that claims 5 and 6 of the Cousino patent No. 1,327,945 are invalid.

Appeal No. 4647. Respecting the four patents involved on this appeal which the District Court held invalid, nothing need be said. Judge Lindley's memorandum covers each of them, and we approve of his conclusions and his reasoning.

The appeal in No. 4647 is affirmed.

The appeal in No. 4646 is affirmed so far as the decree of the District Court relates to patents owned by Unity Manufacturing Company upon which it brought suit. The decree in favor of International Spotlight Corporation and the Lorraine Corporation sustaining the Cousino patent No. 1,327,945 is reversed with directions to enter a decree in accordance with the views expressed in this opinion.

The costs of the two appeals shall be equally divided between the parties.

Patent Office Board of Appeals

EX PARTE ARTHUR L. DOTTER

Appeal No. 2432 Decided Dec. 10, 1931

The United States Daily, March 14, 1932

Patents—Claims—Miscellaneous Objections—Words and Phrases—

Claim includes expression "loose granules of a natural material of the group comprising wood and grains;" word "comprising" does not exclude other materials

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7 is affirmed. 6 is affirmed so District Court ed by Unity upon which it ee in favor of Corporation and ion sustaining 1,327,945 is re- enter a decree views expressed

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besides wood and grains; word "consisting" would confine material strictly to wood, and grains; if amended, claim may be allowed.

Patents—Purifying Air Claims Allowed—

Patent 1847297, Dotter, Method of and Apparatus for Purifying Air, claims 17 and 18 of application allowed; claims 14 to 16 refused.

Patent No. 1847297 was issued March 1, 1932, for method of and apparatus for purifying air, on application filed March 7, 1928. Serial No. 259707.

BROWN & CRITCHLOW for applicant.

Before MOORE, Assistant Commissioner, and REDROW and EDINBURG, Examiners in Chief.

REDROW, Examiner in Chief.—This is an appeal from the final rejection of claims 14 to 18, inclusive.

Claims 14, 17 and 18 are illustrative:

14. The method of purifying air containing an irritant dispersed as a liquid phase therein to render the air suitable for breathing, comprising leading the air through a mass of granules of natural polyosic material to remove said liquid phase irritant from the air, said mass presenting a large exposed surface area relative to its weight without causing undue resistance to passage of the air through it.

17. An apparatus for purifying air containing an irritant dispersed as a liquid phase therein to render the air suitable for breathing, comprising a canister adapted for the passage of air therethrough, and having therein a mass of loose granules of a natural material of the group comprising wood and grains, said mass presenting a large exposed surface area relative to its weight and being effective to remove said liquid phase irritant from air passed through the canister, the canister having a low breathing resistance.

18. An apparatus for purifying air containing an irritant dispersed as a liquid phase therein to render the air suitable for breathing, comprising a canister adapted for the passage of air therethrough, and having therein a mass of loose granules of sawdust, said mass presenting a large exposed surface area relative to its weight and being effective to remove said liquid phase irritant from air passed through the canister, the canister having a low breathing resistance.

The references relied on by the Examiner are:

Temple, 977,907, Dec. 6, 1910;
Bevan, 1,223,244, Apr. 17, 1917.
Levy, 1,414,194, Apr. 25, 1922.

This application discloses a method and apparatus for purifying air. It re-

lates particularly to the contents of the canister associated with gas masks for firemen and mine rescue workers. In addition to the usual contents of such canister, which are materials for combining with and retaining fumes of acids and alkalis as well as mechanically entrapping smoke and dust, applicant provides a layer of polyosic material which he states may comprise crushed cellular cereal grains and cellulose. It is stated that these are particularly effective in absorbing and retaining fumes from heated phenolic condensation products or synthetic resins, thereby making the canister particularly effective for use by firemen where electrical apparatus such as switch boards and the like are involved. Applicant's original specification stated that cracked or crushed cereal grains, wood sawdust and purified cellulose cotton might be used. We understand that the latter term would include cotton and refined wood pulp.

The patent to Levy discloses the use of cotton-wool or cellulose wadding as one of the materials to be used in these canisters. According to applicant's original disclosure this appears to be anticipation of his disclosed cellulose cotton set forth as an equivalent of sawdust or crushed grain. This appears therefore to anticipate any method disclosed in the application as broadly passing air through this class of material. If this class of chemical material, polyosic, has such affinity for fumes of condensation products, it is as effective and true of Levy as in applicant's case. The degree of resistance to breathing is immaterial in the process.

We consider that the method claims 14, 15 and 16 are anticipated.

Claims 17 and 18 are directed particularly to a canister having therein a mass of loose granules of sawdust specifically or of the group consisting of wood and grains. Claim 18 is believed allowable over Levy and also over Bevan showing sawdust which has been treated with a strong solution of caustic alkali. This treatment would hydrate the cellulose and fill up the pores with alkali and it is not clear that it would be the equivalent of untreated sawdust. The patent to Temple relates to an apparatus for producing fuel gas and is not regarded as an analogous art. Claim 17 includes

the expression, "loose granules of a natural material of the group comprising wood and grain". The word "comprising" does not exclude other materials besides wood and grains. It is considered that the word "consisting" would be more appropriate in this relation in confining the material strictly to these materials

—wood and grains. If this formal change is made in claim 17 it may be allowed.

The decision of the Examiner is affirmed as to claims 14, 15 and 16, but is reversed as to claims 17 and 18 subject to the formal correction of claim 17 suggested.

District Court, D. Maine
AMERICAN CRAYON COMPANY v. PRANG COMPANY
Equity No. 899 Decided February 18, 1932

Trade Marks—Assignments—

Granting clause of trade mark assignment specifically excepts certain goods and so did not transfer entire business although whereas clause mentioned entire business.

Trade Marks—Res Adjudicata—

Where plaintiff and defendant's assignee have had litigation in U. S. courts involving use and rights to use of trade marks, the decision there is res adjudicata to present suit for breach of contract involving the same trade mark, which contract was made long before the other suit.

Trade Marks—Assignments—Parties Liable—

Where defendant, a Maine Corporation, sold certain trade mark rights to plaintiff and then sold balance of its rights to Delaware Corporation, there was privity between defendant and Delaware Corporation, but defendant can not be held responsible for wrongful use of assigned rights since it is not known that defendant was in control of Delaware Corporation.

HALE, District Judge.—The plaintiff, an Ohio corporation, brings this suit in equity against the defendant, a Maine corporation, for breach of a contract dated March 1st, 1918, by which the Maine corporation is alleged to have assigned to the plaintiff all its right in the trademark "Prang" and monogram "P. Co." in certain commodities. Plaintiff seeks an injunction, an accounting and other equitable relief. The original bill was filed in this Court on October 15, 1926. The defendant answered, setting up a decree of the United States District Court of Delaware dismissing the bill in equity against the defendants' assignee, the Prang Company of Delaware, and asserting a privity between the Prang Company of Delaware and the Prang Company of Maine. The Delaware case was for trademark infringement and unfair competition, brought by this plaintiff against the Prang Company of Delaware. After final decree by the United States Circuit Court of Appeals for the Third Circuit, the plaintiff filed a supplementary bill setting up that decree and subsequent proceedings. The defendant filed its answer to the supplemental bill. The defendant claims that the Delaware litigation is a complete settlement of this litigation; that the plaintiff elected to settle the case by the Delaware suit,

has got the full benefit of that suit; and that the whole matter is *res adjudicata*.

The case came to trial in this Court in September, 1931. Plaintiff examined one witness and brought before this Court all the proceedings of the Delaware case, claiming that it brought this record before this Court for the limited purpose of establishing *res adjudicata* of certain facts there decided.

Defendant offered no proofs.

There is a dispute as to what passed by the defendant to the plaintiff under the contract in question. The plaintiff urges that the whole contract taken together should be construed to pass to the plaintiff from the defendant all the business in artist and school supplies and commodities, and that practically the whole business passed in its entirety to the plaintiff; that the "Whereas" clauses of the contract allege that the Prang Co. has been dealing in artist and school supplies for many years and that they clearly indicate that it is the intention of the defendant to pass the whole business of artist and school supplies to the plaintiff. I cannot sustain this contention. The granting clause of the contract is as follows:

"1. The Prang Company does hereby agree to sell and by these presents does hereby sell unto The American

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same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

In product claim 1 appellants have "fingerprinted" their crystalline zeolitic aluminosilicate by reciting six parameters, two directly compositional in nature, $\text{SiO}_2/\text{Al}_2\text{O}_3$ and $\text{Na}_2\text{O}/\text{Al}_2\text{O}_3$ molar ratios. The other parameters are the cubic unit cell size (ao), the ion exchange capacity, the oxygen adsorption capacity, and the X-ray powder diffraction pattern. Hansford discloses $\text{SiO}_2/\text{Al}_2\text{O}_3$ and $\text{Na}_2\text{O}/\text{Al}_2\text{O}_3$ molar ratios within the ranges recited in claim 1, but does not specifically disclose the other parameters.

Though urging that the other parameters are the unique result of their claimed process, appellants have offered no comparison of those other parameters with the corresponding parameters of Hansford's product.

We affirm the decision of the board upholding the rejections of product claims 1-2 on Hansford and do not reach the rejections of claims 1-2 on Maher, McDaniel, Kerr I, or Kerr II.

The decision of the board is affirmed.

Court of Customs and Patent Appeals

In re Driscoll

No. 77-560 Decided Oct. 6, 1977

PATENTS

1. Application for patent — Continuing (§15.3)

Construction and specification of claims — In general (§22.01)

Specification — Sufficiency of disclosure (§62.7)

Earlier filed application's disclosure must be viewed as it would be by person skilled in art to determine whether it reasonably conveys information that as of its filing date

applicant possessed class of compounds defined in present claim, to determine if applicant is entitled to earlier filing date.

2. Claims — Broad or narrow — Markush type (§20.205)

It is generally understood that in so describing class of compounds applicant is, in effect, asserting that members of Markush group do not fall within any recognized generic class, but are alternatively usable for purposes of invention, and therefore, regardless of which of alternatives is substituted on basic structure, compound as whole will exhibit disclosed utility.

3. Specification — Sufficiency of disclosure (§62.7)

Each case involving questions of compliance with 35 U.S.C. 112 description requirement must be decided on its own facts, so that precedential value of cases in this area is extremely limited.

4. Disclaimer — In general (§32.1)

Pleading and practice in Patent Office — Rejections (§54.7)

Applicant's failure to file terminal disclaimer in parent application is not proper basis for rejecting continuation in part application on grounds of obviousness-type double patenting.

Particular patents — 5-Substituted Thiadiazole Ureas

Driscoll, 5-Substituted Thiadiazole Ureas and Their Use as Herbicides, rejection of claim 13 reversed.

Appeal from Patent and Trademark Office Board of Appeals

Application for patent of Patrick R. Driscoll, Serial No. 316,794, filed December 20, 1972. From decision rejecting claim 13, applicant appeals. Reversed.

Michael G. Gilman, Palisades, N.Y., for applicant.

Joseph F. Nakamura (Jack E. Armore, of counsel) for Commissioner of Patents and Trademarks.

Before Markey, Chief Judge, Rich, Baldwin, and Miller, Associate Judges, and Almond, Senior Judge.

Almond, Senior Judge.

This is an appeal from the decision of the Patent and Trademark Office (PTO) Board.

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decision of the: (PTO) Board:

of Appeals (board) affirming the rejection of claim 13 of appellant's application, serial No. 316,794, filed December 20, 1972, for "5-Substituted Thiadiazole Ureas and Their Use as Herbicides." We reverse.

The Invention

The invention relates to 5-alkylsulfonyl-1,3,4-thiadiazole ureas which are useful in controlling undesired plant growth.

The appealed claim (paragraphing supplied) reads:

13. A Compound of the Formula



wherein R is alkylsulfonyl (C₁-C₈);

R₁ is selected from the group consisting of H, alkyl (C₁-C₈), and cycloalkyl (C₃-C₆);

R₂ is from the group consisting of H, alkyl (C₁-C₈), haloalkyl (C₁-C₈), alkoxy (C₁-C₈), alkenyl (C₂-C₈), alkynyl (C₂-C₈), aryl, and haloaryl, and wherein R₁ and R₂ are alkylene which, together with N, form a ring of at least 3, but not more than 6 members;

R₃ is H or alkyl (C₁-C₈); and X is selected from the group consisting of oxygen and sulfur.

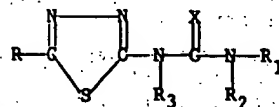
Background

Pursuant to 35 USC 120,² appellant has claimed the benefit of an earlier filing date based on a series of previously filed applications, the present application being designated a continuation-in-part of application serial No. 113,679, filed February 8, 1971 (S.N. 113,679), which is a

continuation-in-part of application serial No. 818,078, filed April 21, 1969; which, in turn, is a continuation-in-part of application serial No. 782,756, filed December 10, 1968 (S.N. 782,756).¹

S.N. 782,756 contains the following disclosure relied on by appellant to support his claim under §120:

In accordance with the invention, there is provided a compound of the formula [paragraphing supplied]:



wherein R is selected from the group consisting of H, alkyl (C₁-C₈), haloalkyl (C₁-C₈), cycloalkyl (C₃-C₆), halocycloalkyl (C₃-C₆), alkoxy, alkoxyalkyl, alkoxyalkylthio, aryl, substituted aryl, alkenyl (C₂-C₈), alkylthio (C₂-C₈), alkylsulfoxide (C₁-C₈), and alkylsulfonyl (C₁-C₈);

R₁ is selected from the group consisting of H, alkyl (C₁-C₈), and cycloalkyl (C₃-C₆);

R₂ is from the group consisting of H, alkyl (C₁-C₈), haloalkyl (C₁-C₈), alkoxy (C₁-C₈), alkenyl (C₂-C₈), alkynyl (C₂-C₈), aryl and haloaryl, and wherein R₁ and R₂ are alkyl which, together with N, form a ring of at least 3, but not more than 6 members;

R₃ is H or alkyl (C₁-C₈); and X is selected from the group consisting of oxygen and sulfur.

Original claim 1 of S.N. 782,756 is a verbatim recitation of the above structural formula.⁴

¹ Mobil Oil Corp. is the real party in interest.

² Section 120 provides:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

The first paragraph of section 112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

³ The "genealogy" of the present application can be traced through additional earlier filed applications, the disclosures of which are irrelevant to the present controversy.

⁴ The basic structure of the compounds here involved may be viewed as a combination of two distinct moieties:

Proceedings in the PTO

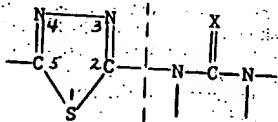
Claim 13 was rejected under 35 USC 102 as anticipated by Belgian patent No. 743,615, the effective reference date of which is June 23, 1970. The examiner took the position that appellant was not entitled to the benefit of a filing date prior to the reference date because nowhere in appellant's earlier filed applications was there a written description of the subject matter of claim 13 in "full, clear, and exact terms," as required by 35 USC 112. According to the examiner:

One skilled in the art reading [the portion of the disclosure of S.N. 782,756 relied on by appellant] would simply not conceive of, without more, the new genus reflected in instant claim 13. [Emphasis in original.]

Accordingly, the examiner concluded that inasmuch as the reference discloses several compounds embraced by the appealed claim and has an effective date more than one year prior to the filing date of the present application, it constitutes a statutory bar under §102.

In sustaining the examiner's rejection, the board stated:

In view of the relatively large number of possible values for R₁ and in the absence of anything in the disclosure to direct one specifically to the subgenus where R is alkylsulfonyl, we cannot agree with appellant's position. * * * To hold otherwise would be to find within appellant's generic description also a description of each subgenus wherein R₁ was selected from a single member of the group disclosed, while retaining the generic description of the remaining variable symbols, and each subgenus obtained by carrying out a similar operation with R₂ and R₃ and X. We think it clear that the single generic description relied



The portion on the left is a thiadiazole moiety which is a five-membered heterocycle, the members of which have been numbered in accordance with convention. When X is oxygen, the portion on the right is a urea moiety, urea having the formula $\text{NH}_2\text{CO-NH}_2$. When X is sulfur, the portion on the right is a thiourea moiety.

on, in the absence of any additional subgeneric disclosure, is incapable of constituting a written description of so many different genera or subgenera of chemical compounds in the manner required by the statute.

The examiner also rejected claim 13 on the ground of double patenting over the claims of S.N. 113,679. 35 USC 101³ was cited as the statutory basis of rejection.⁴ However, the board sustained the rejection on a different basis, stating that:

The examiner has incorrectly cited 35 U.S.C. 101 as the basis of his rejection. Although claims 1, 9, 19 and 20 of the co-pending, earlier filed application read on subject matter comprehended by the claim here on appeal, none of the former claims are equivalent in scope to the latter claim. Thus the claims of the parent application are not drawn to the same invention as the claim before us, and 35 U.S.C. 101 is not applicable. However, the judicially created doctrine of double patenting of the obviousness type is clearly appropriate in this situation, as appellant is evidently aware since a terminal disclaimer has been filed in this case. [Citations omitted.] Inasmuch as no terminal disclaimer has been filed in the parent application, however, the potential extension of monopoly upon which this rejection is grounded has not been obviated, and the examiner's rejection must be affirmed.

³ Section 101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

⁴ In the examiner's Answer, appellant was required for the first time to eliminate the conflicting claims from all but one of the copending applications pursuant to 37 CFR 1.78(b), which provides:

Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

Appellant responded to this requirement in his reply brief by electing to prosecute the claims in the present application and indicating that the conflicting claims in S.N. 113,679 would be canceled "at an appropriate time."

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Claim 13 was further rejected "as being unpatentable over a count of Interference No. 98,209," as well as on the grounds that the present specification provides inadequate enabling support for the full scope of the claim (35 USC 112, first paragraph) and that the claim fails "to define the invention clearly" (35 USC 112, second paragraph). The board reversed the latter rejections.

Opinion

The 35 USC 102 rejection.

Appellant does not dispute that the appealed claim is anticipated by the Belgian patent if the present application is not entitled to the earlier filing date of S.N. 782,756. Consequently, the sole issue with respect to this aspect of the appeal is whether the disclosure of S.N. 782,756 describes the subject matter of claim 13.

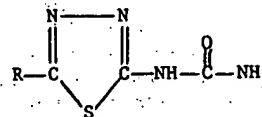
[1] In resolving this issue, we must view the disclosure of the earlier filed application as would a person skilled in the art and determine whether it reasonably conveys the information that as of the filing date thereof appellant had possession of the class of 5-alkylsulfonyl-1,3,4-thiadiazole ureas defined in claim 13. We are satisfied that it does.

A comparison of the appealed claim with the class of compounds disclosed in S.N. 782,756 reveals that the only difference therebetween lies in the definition of the substituent designated by R. In the appealed claim, R is simply alkylsulfonyl (C₁-C₈), whereas in the earlier application, R corresponds to a Markush group of fourteen variable substituents (the R group), one of which is alkylsulfonyl (C₁-C₈).

[2] The practice of describing a class of chemical compounds in terms of a structural formula wherein the substituents thereof are defined as "a member selected from the group consisting of A, B, C, D, * * *" was sanctioned by implication in *Ex parte Markush*, 1925 C.D. 126, 340 O.G. 839, the first decision to consider the propriety of claims so expressed — hence, the name "Markush group." It is generally understood that in thus describing a class of compounds an applicant is, in effect, asserting that the members of the Markush group

do not fall within any recognized generic class, but are alternatively usable for the purposes of the invention, and therefore, regardless of which of the alternatives is substituted on the basic structure, the compound as a whole will exhibit the disclosed utility.

An example will serve to illustrate this point. Assume that instead of the foregoing structural formula, S.N. 782,756 expressly disclosed a class of herbicides represented by the formula



"wherein R is selected from the group consisting of H, alkyl (C₁-C₈), haloalkyl (C₁-C₈), cycloalkyl (C₃-C₆), * * * alkylsulfonyl (C₁-C₈)" (i.e., R as defined in S.N. 782,756). Given the rationale underlying the use of Markush groups, one skilled in the art would view the above formula as a description of fourteen distinct classes of 5-substituted thiadiazole ureas, each possessing herbicidal activity, just as if the application had listed a first structural formula wherein R was hydrogen, a second wherein R was alkyl (C₁-C₈), a third wherein R was haloalkyl (C₁-C₈), and so on.

Although the preceding example was adduced for illustrative purposes, we believe that, in reality, the exemplified structural formula constitutes the essence of appellant's invention and that one skilled in the art would recognize it as such from the earlier filed application.

S.N. 782,756 points up appellant's contribution to the art with the statement that:

Particularly effective [herbicides] are [thiadiazole ureas] which contain an organic substituent in the 5-position of the thiadiazole portion.

Thus, the focus is unquestionably on the substituents at the 5-position of the thiadiazole moiety, and not on the substituents of the urea moiety. Accordingly, one skilled in the art would regard the structural formula of S.N. 782,756 as signifying that no matter which member of the R group is present on the thiadiazole moiety, the urea moiety may be substituted or unsubstituted.

We thus agree with appellant that a skilled artisan would recognize from the disclosure of S.N. 782,756 fourteen distinct classes of compounds, each class having a

³ S.N. 113,679 was involved in Interference No. 98,209. Prior to the board's decision, but subsequent to the mailing of the examiner's Answer, the interference was terminated in appellant's favor. Accordingly, the board considered the rejection moot.

single member of the R group at the 5-position of the thiadiazole moiety and variable substituent groups on the urea moiety. This being the case, it follows that S.N.782,756 describes the subject matter of claim 13 inasmuch as one of the fourteen classes of compounds is the 5-alkylsulfonyl-1,3,4-thiadiazole ureas defined therein.

This record presents yet another instance of the sort of "hypertechnical" application" of the written description requirement of §112 which was recently criticized in *In re Johnson*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977).⁴ Were the board's decision permitted to stand, future applicants, particularly in cases of this nature, would in all likelihood find themselves in the predicament reflected in the following observation, by Judge Learned Hand:

If, when [applicants] yield any part of what they originally believed to be their due, they substitute a new "invention," only two courses will be open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to dis-

credit it. *It is impossible to imagine any public purpose which it could serve.* [Emphasis added.]

Engineering Development Laboratories v. Radio Corp. of America, 153 F.2d 523, 526-27, 68 USPQ 238, 241-242 (CA2 1946).

Aside from reiterating the reasons advanced by the board for affirming the examiner's rejection, the solicitor asserts that *In re Ruschig*, 54 CCPA 1551, 379 F.2d 990, 154 USPQ 118 (1967), "may be considered controlling in the present appeal." We disagree.

Ruschig involved a claim drawn to a single compound, N-(p-chlorobenzenesulfonyl)-N'-propylurea (the structure of which is reproduced in the opinion). The PTO rejected that claim, which was added by amendment, contending that it was not described in the application as originally filed. As presently pointed out by the solicitor, one of the arguments there advanced to overcome the rejection was that the subject matter of the appealed claim was described in an original claim setting forth the structural formula of a benzenesulfonyl-urea having two variable substituents defined as Markush groups. Any seeming similarity between *Ruschig* and the present case is illusory, however, because the structural formula there relied on could have described, at best, only a subgenus including the specific compound claimed, and not the compound itself. In this respect, *Ruschig* is readily distinguishable from the present case where the exact subgenus claimed is clearly discernible in the generalized formula of the thiadiazole urea set forth in the earlier filed application.

[3] Moreover, it should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of §112 that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

Upon the facts of this case, we conclude that the subject matter of claim 13 is described in S.N.782,756. The other requirements of 35 USC 120 presumably having been met, the present application is entitled to the benefit of a filing date prior to the effective date of the Belgian patent. Accordingly, we reverse the rejection of claim 13 under 35 USC 102.

The double patenting rejection.

Although appellant questions the propriety of rejecting claims in one application on

⁴ In that case a class of thermoplastic polyarylene polyethers was disclosed and claimed in a 1963 application which became involved in an interference, the award of priority therein being adverse to Johnson and Farnham. The sole interference count recited a single species within the class of polyethers originally claimed. In 1972 a continuation-in-part application was filed containing claims which differed from the broad claims of the earlier application by reciting a proviso that excluded, *inter alia*, the subject matter of the lost count. Those claims were rejected under 35 USC 102 on the basis of a Netherlands patent, which was a counterpart of the 1963 application. There, as here, the benefit of an earlier filing date was denied because the newly claimed subject matter was allegedly not described in the earlier application. In reversing the rejection, the court there observed that the applicants were merely excising the invention of another, to which they were not entitled, rather than creating an artificial subgenus or claiming new matter.

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the grounds of obviousness type double patenting over claims of a copending application of the same inventor, we leave the resolution of this issue for another day. We choose instead to assume, arguendo, that claim 13 has been properly rejected and to consider whether appellant's terminal disclaimer under 35 USC.253⁹ overcomes the rejection.

As was stated in *In re Thorington*, 57 CCPA 759, 765, 418 F.2d 528, 534, 163 USPQ 644, 648 (1969):

[D]ouble patenting rejections usually take one or both of two forms, namely, the "same invention" type "double patenting" identifiable with the statutory provision 35 U.S.C. 101, saying that an inventor may obtain a patent, interpreted as meaning only one patent; and the "obviousness" type "double patenting," a judicially-created doctrine grounded in public policy rather than statute and primarily intended to prevent prolongation of monopoly by prohibiting claims in a second patent not patentably distinguishing from claims of a first patent. This court has held that a terminal disclaimer is ineffective where it is attempted to twice claim the same invention; however, an "obviousness" type "double patenting" rejection may be obviated by a terminal disclaimer. [Emphasis in original.]

[4] As previously indicated, notwithstanding the examiner's citation of 35 USC 101, the board relied on the judicially-created doctrine of obviousness-type double patenting in upholding the rejection of claim 13 over certain claims of S.N.113,679.¹⁰ As to

⁹ Section 253 provides:

Whenever, without any deceptive intention, a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid: A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted. [Emphasis added.]

¹⁰ S.N.113,679; claims 1, 9, 19, and 20 of which were cited by the board in upholding the double

the effect of appellant's filing of a terminal disclaimer in the present application; however, the board maintained that since no terminal disclaimer had been filed in S.N.113,679, "the potential extension of monopoly upon which this rejection is grounded has not been obviated * * *." We consider this line of reasoning unsound, inasmuch as the claim in this application, which is all that we are presently concerned with, is subject to the terminal disclaimer. If the present application should go to issue during the pendency of S.N.113,679, and the latter contains potentially conflicting claims, the proper procedure would be, at that time, to reject those claims for double patenting over the claim of the present application. Appellant's failure to file a terminal disclaimer in S.N.113,679 at this time cannot justify the denial of the claim here on appeal. Accordingly, we reverse the double patenting rejection.

Court of Customs and Patent Appeals

In re de Castelet

No. 76-699 Decided Oct. 6, 1977

PATENTS

1. Patentability—Subject matter for patent monopoly — In general (§51.601)

Analysis under Section 101 must be directed to claimed subject matter as whole; suggestion that piecemeal analysis is either useful or appropriate is rejected.

2. Patent grant — Intent of patent laws (§50.15)

Patentability—Subject matter for patent monopoly — In general (§51.601)

No basis exists for moratorium on protection of inventions embodying or using computer programs, absent contrary directions;

patenting rejection, does not appear in the record. However, since appellant has failed to argue otherwise, we assume that the appealed claim is a mere obvious variant of the cited claims.

present. For these reasons, the court adopts the modified jurisdiction test.⁷

[2] The court determines, without hesitation, that Turbo Tek has the continuous and systematic contacts with North Carolina necessary to support general jurisdiction and thus venue. In the last year, Turbo Tek has sold in North Carolina 30,570 of its pressure washers, 24,720 bottles of soft suds, 7,164 bottles of hard suds, 81,678 bottles of exploding wax, and 864 unspecified products. North Carolina accounts for 3.6% of Turbo Tek's total sales, yielding Turbo Tek over \$300,000.00 in the last year. Turbo Tek transports these goods directly from its facilities in California to its customers in North Carolina. In addition, Turbo Tek has a sales representative who permanently resides in North Carolina and solicits sales throughout the state. Turbo Tek's Vice

⁷ The Fourth Circuit has not explicitly addressed the proper test for determining "doing business" venue. The two Fourth Circuit cases mentioning "doing business" venue have merely recited the contacts with the forum and then concluded that venue is proper. See *In Re Ralston Purina Co.*, 726 F.2d 1002, 1003 (4th Cir. 1984) (recites contacts and then merely states that "Purina is doing business" under 28 U.S.C. §1391(c)); *Du-Al Corp. v. Rudolph Beaver, Inc.*, 540 F.2d 1230, 1231, 1233 (4th Cir. 1976) (recites contacts then merely states that "collectively these activities constituted 'doing business'"). Arguably, by explaining that the contacts satisfied personal jurisdiction and then concluding that these same contacts amounted to "doing business", *Du-Al* equates venue and personal jurisdiction. A few cases have interpreted *Du-Al* as equating venue and personal jurisdiction. See e.g. *Precision Rubber Products v. George McCarthy, Inc.*, 605 F.Supp. 473, 477 (M.D.Tenn. 1984); 1985; *Witzel v. Chartered Systems Corp. of N.Y.*, 490 F.Supp. 343, 348 (D.Minn. 1980). See also Note, 65 Tex.L.Rev. at n.57 and accompanying text (interprets *Du-Al* as equating venue and personal jurisdiction). Yet, a recent case states that *Du-Al* "might be said to have adopted this view [i.e. the jurisdiction test] although less clearly, and with less discussion [than the other cases adopting the view]." *Maybelline Co.*, 813 F.2d at n.5 [2 USPQ2d at 1127 n.5] (emphasis added). Moreover, *Du-Al* was decided before the Supreme Court, in *Leroy*, expressed that venue statutes are designed to protect the defendant from an inconvenient forum. In sum, given the inexplicitness of *Du-Al*, the conflicting interpretations of *Du-Al* by other courts, and the fact *Du-Al* was decided before *Leroy*, this court may appropriately attempt to refine the "doing business" standard in the this circuit. As such, the court herein adopts the modified jurisdiction test. The court notes, however, that venue is proper in the instant case under either the jurisdiction or the modified jurisdiction test.

President has, on at least one occasion, visited customers within North Carolina. Furthermore, Turbo Tek has run television advertisements on seventeen local television stations in North Carolina. Finally, Turbo Tek operates a mail order business, under the name Distribution Systems International, that has received and honored mail orders from North Carolinians. The court, accordingly, concludes that under the modified jurisdiction test Turbo Tek is "doing business" in North Carolina, thereby establishing venue under §1391(c).⁸

CONCLUSION

The court concludes that plaintiff complied with Fed.R.Civ.P. 4(c)(2)(C)(ii) in personally serving defendant, outside the forum state, with notice of this action. The court further concludes that defendant is "doing business" in North Carolina and thus venue is proper under 28 U.S.C. §1391(c). The court, accordingly, denies defendant's motion to dismiss.

Court of Appeals, Federal Circuit

In re Fine

No. 87-1319

Decided January 26, 1988

PATENTS

1. Patentability/Validity — Obviousness — Evidence of (§115.0903)

Patent and Trademark Office improperly rejected claimed invention for obviousness since nothing in cited references, either alone or in combination, suggests or teaches claimed invention, since there is consequently no support for PTO's conclusion that substitution of one type of detector for another in prior art system, resulting in claimed invention, would have been obvious, and since PTO therefore failed to satisfy its burden of establishing prima facie case of obviousness by showing some objective teaching or gener-

⁸ Because the court finds venue proper under §1391(c), it will not address whether the claims herein arose in North Carolina. See 28 U.S.C. §1391(b).

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— Obviousness — (103)

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ally available knowledge that would lead one skilled in art to combine teachings of existing references.

2. Patentability/Validity — Obviousness — In general (§115.0901)

Obviousness is tested by what combined teachings of prior art references would have suggested to those of ordinary skill in art, not by whether particular combination of elements from such references might have been "obvious to try."

3. Patentability/Validity — Obviousness — Evidence of (§115.0903)

Patent and Trademark Office erred, in rejecting as obvious system for detecting and measuring minute quantities of nitrogen compounds, by failing to recognize that appealed claims can be distinguished over combination of prior art references, in view of evidence demonstrating that prior art does not teach claimed temperature range, despite some overlap of preferred temperature ranges for claimed invention and prior art, since purposes of preferred temperature ranges are different and overlap is mere happenstance.

4. Patentability/Validity — Obviousness — In general (§115.0901)

Dependent claims are non-obvious under 35 USC 103 if claims from which they depend are non-obvious.

Appeal from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Application for patent by David H. Fine, Serial No. 512,374. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicant appeals. Reversed; Smith, circuit judge, dissenting with opinion.

Morris Relson and Darby & Darby, New York, N.Y., (Beverly B. Goodwin with them on the brief) for appellant.

Lee E. Barrett, associate solicitor, Arlington, Va., (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief) for appellee.

Before Friedman, Smith, and Mayer, circuit judges.

Mayer, J.

David H. Fine appeals from a decision of the Board of Patent Appeals and Interfer-

ences of the United States Patent and Trademark Office (Board) affirming the rejection of certain claims of his application, Serial No. 512,374, and concluding that his invention would have been obvious to one of ordinary skill in the art and was therefore unpatentable under 35 U.S.C. §103. We reverse.

Background

A. The Invention.

The invention claimed is a system for detecting and measuring minute quantities of nitrogen compounds. According to Fine, the system has the ability to detect the presence of nitrogen compounds in quantities as minute as one part in one billion, and is an effective means to detect drugs and explosives, which emanate nitrogen compound vapors even when they are concealed in luggage and closed containers.

The claimed invention has three major components: (1) a gas chromatograph which separates a gaseous sample into its constituent parts; (2) a converter which converts the nitrogen compound effluent output of the chromatograph into nitric oxide in a hot, oxygen-rich environment; and (3) a detector for measuring the level of nitric oxide. The claimed invention's sensitivity is achieved by combining nitric oxide with ozone to produce nitrogen dioxide which concurrently causes a detectable luminescence. The luminescence, which is measured by a visual detector, shows the level of nitric oxide which in turn is a measure of nitrogen compounds found in the sample.

The appealed claims were rejected by the Patent and Trademark Office (PTO) under 35 U.S.C. §103. Claims 60, 63, 77 and 80 were rejected as unpatentable over Eads, Patent No. 3,650,696 (Eads) in view of Warnick, et al., Patent No. 3,746,513 (Warnick). Claims 62, 68, 69, 79, 85 and 86 were rejected as unpatentable over Eads and Warnick in view of Glass, et al., Patent No. 3,207,585 (Glass).

B. The Prior Art.

1. Eads Patent.

Eads discloses a method for separating, identifying and quantitatively monitoring sulfur compounds. The Eads system is used primarily in air pollution control work in the scientific characterization of odors from sulfur compounds.

The problem addressed by Eads is the tendency of sulfur compounds "to adhere to or react with the surface materials of the sampling and analytical equipment, and/or react with the liquid or gaseous materials in the equipment." Because of this, the accura-

cy of measurement is impaired. To solve the problem, the Eads system collects an air sample containing sulfur compounds in a sulfur-free methanol solution. The liquid is inserted into a gas chromatograph which separates the various sulfur compounds. The compounds are next sent through a pyrolysis furnace where they are oxidized to form sulfur dioxide. Finally, the sulfur dioxide passes through a measuring device called a microcoulometer which uses titration cells to calculate the concentration of sulfur compounds in the sample.

2. Warnick Patent.

Warnick is directed to a means for detecting the quantity of pollutants in the atmosphere. By measuring the chemiluminescence of the reaction between nitric oxide and ozone, the Warnick device can detect the concentration of nitric oxide in a sample gaseous mixture.

Warnick calls for "continuously flowing" a sample gaseous mixture and a reactant containing ozone into a reaction chamber. The chemiluminescence from the resulting reaction is transmitted through a light-transmitting element to produce continuous readouts of the total amount of nitric oxide present in the sample.

3. Glass Patent.

The invention disclosed in Glass is a device for "completely burning a measured amount of a substance and analyzing the combustion products." A fixed amount of a liquid petroleum sample and oxygen are supplied to a flame. The flame is then spark-ignited, causing the sample to burn. The resulting combustion products are then collected and measured, and from this measurement the hydrogen concentration in the sample is computed.

C. The Rejection.

The Examiner rejected claims 60, 63, 77 and 80 because "substitution of the [nitric oxide] detector of Warnick for the sulfur detector of Eads would be an obvious consideration if interested in nitrogen compounds, and would yield the claimed invention." He further asserted that "Eads teaches the [claimed] combination of chromatograph, combustion, and detection, in that order. . . . Substitution of detectors to measure any component of interest is well within the skill of the art." In rejecting claims 62, 68, 69, 79, 85 and 86, the Examiner said, "Glass et al. teach a flame conversion means followed by a detector, and substitution of the flame conversion means of Glass et al. for the furnace of Eads would be an obvious equivalent and would yield the claimed invention." The Board affirmed the Examiner's rejection.

Discussion

A. Standard of Review.

Obviousness under 35 U.S.C. §103 is "a legal conclusion based on factual evidence." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983) (quoting *Stevens v. Int'l Trade Comm'n*, 612 F.2d 546, 549, 204 USPQ 276, 279 (CCPA 1979)). Therefore, an obviousness determination is not reviewed under the clearly erroneous standard applicable to fact findings, *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983); it is "reviewed for correctness or error as a matter of law." *In re De Blauwe*, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).

To reach a proper conclusion under §103, the decisionmaker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In light of *all* the evidence, the decisionmaker must then determine whether . . . the claimed invention as a whole would have been obvious at *that* time to *that* person. 35 U.S.C. §103. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1595-96 (Fed. Cir. 1987).

B. Prima Facie Obviousness.

Fine says the PTO has not established a *prima facie* case of obviousness. He contends the references applied by the Board and Examiner were improperly combined, using hindsight reconstruction, without evidence to support the combination and in the face of contrary teachings in the prior art. He argues that the appealed claims were rejected because the PTO thought it would have been "obvious to try" the claimed invention, an unacceptable basis for rejection.

[1] We agree. The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. See *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-87 (Fed. Cir. 1984). It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Lulu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984); see also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*,

776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). This it has not done. The Board points to nothing in the cited references, either alone or in combination, suggesting or teaching Fine's invention.

The primary basis for the Board's affirmation of the Examiner's rejection was that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. The Board reiterated the Examiner's bald assertion that "substitution of one type of detector for another in the system of Eads would have been within the skill of the art," but neither of them offered any support for or explanation of this conclusion.

Eads is limited to the analysis of sulfur compounds. The particular problem addressed there is the difficulty of obtaining precise measurements of sulfur compounds because of the tendency of sulfur dioxide to adhere to or react with the sampling analytic equipment or the liquid or gaseous materials in the equipment. It solves this problem by suggesting that the gaseous sample containing sulfur compounds be absorbed into sulfur-free methanol and then inserted into a gas chromatograph to separate the sulfur compounds.

There is no suggestion in Eads, which focuses on the unique difficulties inherent in the measurement of sulfur, to use that arrangement to detect nitrogen compounds. In fact, Eads says that the presence of nitrogen is undesirable because the concentration of the titration cell components in the sulfur detector is adversely affected by substantial amounts of nitrogen compounds in the sample. So, instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention. See *W. L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983) (error to find obviousness where references "diverge from and teach away from the invention at hand"). In the face of this, one skilled in the art would not be expected to combine a nitrogen-related detector with the Eads system. Accordingly, there is no suggestion to combine Eads and Warnick.

Likewise, the teachings of Warnick are inconsistent with the claimed invention, to some extent. The Warnick claims are directed to a gas stream from engine exhaust "continuously flowing the gaseous mixtures into the reaction chamber" to obtain "con-

tinuous readouts" of the amount of nitric oxide in the sample. The other words, it contemplates measuring the total amount of nitric oxide in a continuously flowing gaseous mixture of unseparated nitrogen constituents. By contrast, in Fine each nitrogen compound constituent of the gaseous sample is retained in the Chromatograph for an individual time period so that each exits in discrete, time-separated pulses.* By this process, each constituent may be both identified by its position in time sequence, and measured. The claimed system, therefore, diverges from Warnick and teaches advantages not appreciated or contemplated by it.

Because neither Warnick nor Eads, alone or in combination, suggests the claimed invention, the Board erred in affirming the Examiner's conclusion that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. *ACS Hosp. Sys.*, 732 F.2d at 1575-77, 221 USPQ at 931-33. The Eads and Warnick references disclose, at most, that one skilled in the art might find it obvious to try the claimed invention. But whether a particular combination might be "obvious to try" is not a legitimate test of patentability. *In re Geiger*, 815 F.2d 868, 688; 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978).

[2] Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." *Id.* Here, the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination.

* The Solicitor argues that the contents of Attachment C of Fine's brief were not before the Board and may not properly be considered here. However, we need not rely on Attachment C. It is merely illustrative of the qualitative separation of nitrogen compounds which occurs in Fine's system. The fact that the various constituents exit at discrete intervals is shown by the specification which was before the Board and which may appropriately be considered on appeal. See, e.g., *Astra-Sjuco, A.B. v. United States Int'l Trade Comm'n*, 629 F.2d 682, 686, 207 USPQ 1, 5 (CCPA 1980) (claims must be construed in light of specification).

§103 is "a factual, evidentiary question." *Quip Corp.*, 5, 218 USPQ 12 F.2d 546, 12 PA 1979). The Board's determination is not an erroneous one. *Raytheon Co.*, 221 USPQ 951, 956, 12 F.2d 546, 12 PA 1979; it is not as a matter of course. 36 F.2d 699, 12 Cir. 1984).

under §103, backward in time by [a person] when the just before it evidence, the determine invention as a matter of course. §103. The makes more of it, for it is an a foundation facts.

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the burden prima facie case. *745 785, 787-87* this burden teaching in ge generally ll in the art ombine the ences. *In re JSPQ 1257, 14shland Oil, 1sties, Inc.,*

But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore*, 721 F.2d at 1553, 220 USPQ at 312-13. It is essential that "the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made ... to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

C. Advantage Not Appreciated by the Prior Art.

[3] The Board erred not only in improperly combining the Eads and Warnick references but also in failing to appreciate that the appealed claims can be distinguished over that combination. A material limitation of the claimed system is that the conversion to nitric oxide occur in the range of 600°C to 1700°C. The purpose of this limitation is to prevent nitrogen from other sources, such as the air, from being converted to nitric oxide and thereby distorting the measurement of nitric oxide derived from the nitrogen compounds of the sample.

The claimed nitric oxide conversion temperature is not disclosed in Warnick. Although Eads describes a preferred temperature of 675°C to 725°C, the purpose of this range is different from that of Fine. Eads requires the 675°C to 725°C range because it affords a temperature low enough to avoid formation of unwanted sulfur trioxide, yet high enough to avoid formation of unwanted sulfides. Fine's temperature range, in contrast, does not seek to avoid the formation of sulfur compounds or even nitrogen compounds. It enables the system to break down the nitrogen compounds of the sample while avoiding the destruction of background nitrogen gas. There is a partial overlap, of course, but this is mere happenstance. Because the purposes of the two temperature ranges are entirely unrelated, Eads does not teach use of the claimed range. See *In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278. The Board erred by concluding otherwise.

D. Unexpected Results.

Because we reverse for failure to establish a *prima facie* case of obviousness, we need not reach Fine's contention that the Board

failed to accord proper weight to the objective evidence of unexpected superior results.

E. The "Flame" Claims.

[4] Claims 62, 68, 69, 79, 85 and 86 relate to the oxygen-rich flame conversion means of the claimed invention. These "flame" claims depend from either apparatus claim 60 or method claim 77. Dependent claims are non-obvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). In view of our conclusion that claims 60 and 77 are nonobvious, the dependent "flame" claims are also patentable.

Conclusion

The Board's decision affirming the Examiner's rejection of claims 60, 62, 63, 68, 69, 77, 79, 80, 85 and 86 of Fine's application as unpatentable over the prior art under 35 U.S.C. §103 is **REVERSED**.

Smith, circuit judge, dissenting.

I respectfully dissent. I am of the firm belief that the prior art references, relied upon by the PTO to establish its *prima facie* case of obviousness, in combination teach and suggest Fine's invention to one skilled in the art. Also, I firmly believe that Fine failed to rebut the PTO's *prima facie* case. On this basis, I would affirm the board's determination sustaining the examiner's rejection, pursuant to 35 U.S.C. §103, of Fine's claims on appeal before this court.

Court of Appeals, Federal Circuit

Advance Transformer Co. v. Levinson

No. 87-1011

Decided January 28, 1988

PATENTS

1. Infringement — Construction of claims (§115.03)

Patent construction — Patent Office proceedings (§125.05)

Patent construction — Prosecution history estoppel (§125.09)

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ratification can be accepted after expiration of the period for applying for renewal or filing an affidavit of continued use, because it is not a requirement of the statute.

In this case, the renewal application filed October 23, 1989, contains a declaration, pursuant to Trademark Rule 2.20, signed by Anna Veronika Murray, dba Murray Space Shoe Corporation, acknowledging co-ownership of the registration with Murray Space Shoe, Inc. and verifying the facts stated in the renewal application. While this document was filed too late to be accepted as a renewal application, it can be accepted for the purpose of ratifying the statements in the application which was filed on August 16, 1988 on behalf of the joint owners of the registration.

Accordingly, the petition is granted. The registration file will be forwarded to the Affidavit-Renewal Examiner, who is directed to consider the renewal application filed August 16, 1988 as being properly executed and filed by the registrant.

Court of Appeals, Federal Circuit

In re Jones

No. 91-1380

Decided February 28, 1992

PATENTS

1. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Claimed novel salt of acid commonly known as "dicamba" is not so closely related in structure to substituted ammonium salts disclosed in prior patent as to be prima facie obvious, since claimed salt is primary amine with ether linkage, whereas diethanolamino salt disclosed in reference patent is secondary amine without ether linkage, since claimed salt is plainly acyclic or linear, whereas morpholino salt, which is only substituted ammonium salt of dicamba with

³ This is not inconsistent with Office practice under Section 1 of the Act. An application for registration, by joint applicants under Section 1 which is signed by only one party is granted a filing date. Additional declarations by the other owner(s) verifying the facts stated in the application must be submitted during prosecution of the application, before the mark can be approved for publication.

ether linkage disclosed in reference patent, is cyclic in structure, and since isopropylamino salt disclosed in reference patent is primary amine, but has iso-structure quite different from that of claimed salt.

2. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Claimed novel salt of acid commonly known as "dicamba" cannot be held prima facie obvious in view of salts disclosed in prior patent, even though claimed salt is member of genus of substituted ammonium salts broadly disclosed in reference patent, since reference discloses potentially infinite genus of "substituted ammonium salts" of dicamba, and lists several such salts, but does not specifically disclose salt claimed in application, and since claimed salt is not sufficiently similar to those disclosed in reference as to render it prima facie obvious.

3. Patentability/Validity — Obviousness — Combining references (§115.0905)

Contention that one skilled in herbicidal art would have been motivated to use, with acid commonly known as "dicamba," substituted ammonium salt such as that disclosed in two prior references does not warrant holding that claimed substituted ammonium salt of dicamba for use as herbicide is prima facie obvious, since there is no suggestion for combining disclosures of those references either in references themselves, which are directed to shampoo additives and production of morpholine, respectively, or in knowledge generally available to those skilled in art.

Appeal from the U.S. Patent and Trade-mark Office, Board of Patent Appeals and Interferences.

Patent application of Rita S. Jones, Michael T. Chirchirillo and Johnny L. Burns, serial no. 07/099,279 (the 2-(2-aminoethoxy)-ethanol salt of dicamba). From decision upholding rejection of only claim in application, applicants appeal. Reversed.

Melvyn M. Kassenoff, East Hanover, N.J. (Gerald D. Sharkin and Richard E. Villa, East Hanover; Joanne M. Giesser, Palo Alto, Calif., with him on brief), for appellant.

Harris A. Pitlock, associate solicitor (Fred E. McKelvey, solicitor, with him on brief; Richard E. Schafer, of counsel), for appellee.

Before Rich, Archer, and Clevenger, circuit judges.

Rich, J.

Rita S. Jones et al. (collectively, Jones) appeal from the April 15, 1991 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), Appeal No. 90-1920, sustaining the rejection of claim 1, the only claim of application Ser. No. 07/099,279, titled "The 2-(2'-Aminoethoxy) — Ethanol Salt of Dicamba," as unpatentable under 35 USC 103. We conclude that the PTO has not presented a *prima facie* case of obviousness, and therefore reverse.

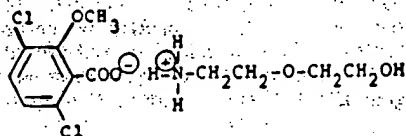
The Invention

The Claimed invention is a novel salt of 2-methoxy-3, 6-dichlorobenzoic acid, which acid is commonly referred to as "dicamba." A known herbicide, dicamba has typically been sold in the form of its known dimethylamine salt.

The sole claim of the application on appeal reads:

1. The 2-(2'-aminoethoxy) ethanol salt of dicamba.

The claimed salt has the following structure:



The Rejection

Claim 1 stands rejected as obvious in view of the combined teachings of the following references:

- Richter, U.S. Patent No. 3,013,054, Dec. 12, 1961.
- Moyle et al., U.S. Patent No. 3,056,669, Oct. 2, 1962.
- Balassa, U.S. Patent No. 3,725,031, Apr. 3, 1973.
- Zorayan et al., 88 *Chem. Abstracts* No. 52300j, 1978.
- Wideman, 86 *Chem. Abstracts* No. 43711a, 1977.

Richter, which all agree is the closest prior art, discloses dicamba in free acid, ester, and salt forms, for use as a herbicide. Among the salt forms disclosed are substituted ammonium salts, a genus which admittedly encompasses the claimed salt. Richter does not specifically disclose the claimed 2-(2'-aminoethoxy) ethanol salt, however. Most

notably, Richter discloses (emphasis and bracketed word ours):

Compositions in which X is substituted ammonium are amine salts of 2-methoxy-3, 6-dichlorobenzoic acid [dicamba] and are prepared by the addition of the free acid to various amines. Typical amines which can be used to prepare such amine salts are dimethylamine, trimethylamine, triethylamine, diethanolamine, triethanolamine, isopropylamine, morpholine, and the like. *The resulting products are, respectively, the dimethylamino, trimethylamino, triethylamino, diethanolamino, triethanolamino, isopropylamino, and morpholino salts of 2-methoxy-3, 6-dichlorobenzoic acid.*

Zorayan teaches the amine (H₂N(CH₂CH₂O)₂H) used to make the claimed salt, as well as the use of that amine in the preparation of surfactants for shampoos, bath preparations, and emulsifiers.

Wideman also teaches the amine disclosed in Zorayan.

The content of the remaining references is unnecessary to our decision.

The Board upheld the examiner's rejection of claim 1 as obvious, finding that the claimed 2-(2'-aminoethoxy) ethanol salt of dicamba and the diethanolamine salt of dicamba specifically disclosed by Richter were "closely related in structure," and that based upon the expectation that "compounds similar in structure will have similar properties," a *prima facie* case of obviousness had arisen. The Board found that Jones' rebuttal evidence (Rule 132 declarations and data reported in the specification) failed to "compare the claimed subject matter with the closest prior art," and accordingly did not serve to rebut the *prima facie* case. This appeal followed.

Analysis

The Solicitor contends that the claimed salt falls within the genus of substituted amine salts of dicamba disclosed by Richter, and that, like Richter's genus, the claimed compound has herbicidal activity. Thus, the Solicitor urges, under the circumstances of this case, (1) the genus/species relationship and (2) the common utility of the claimed and prior art compounds support the Board's holding of *prima facie* obviousness. Moreover, the Solicitor adds, although the claimed compound is neither a homolog nor a position isomer of those salts specifically disclosed in Richter, it is structurally similar thereto, particularly the diethanolamino salt noted by the Board.

s (emphasis and

h X is substituted salts of 2-methoxy acid [dicamba] by the addition of the amines. Typical used to prepare such ylamine, trimethyl-, diethanolamine, pyramine, morpho- resulting products imethylamino, trimino, diethanol-, isopropylamino, of 2-methoxy-3,

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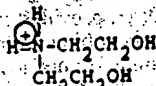
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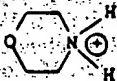
is that the claimed enus of substituted disclosed by Richter, genus, the claimed al activity. Thus, the he circumstances of /species relationship tility of the claimed s support the Board's obviousness. More- adds, although the either a homolog nor ose salts specifically s structurally similar : diethanolamino salt

The question of "structural similarity" in chemical patent cases has generated a body of patent law unto itself. Particular types or categories of structural similarity without more have, in past cases, given rise to *prima facie* obviousness; see, e.g., *In re Dillon*, 919 F.2d 688, 692-94, 16 USPQ2d 1897, 1900-02 (Fed. Cir. 1990) (tri-orthoesters and tetra-orthoesters); *cert. denied*, ___ U.S. ___, 111 S. Ct. 1682 (1991); *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers); *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) (adjacent homologs and structural isomers); *In re Hoch*, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970) (acid and ethyl ester). However, none of these types of structural similarity are involved here. And in any event, this court has previously stated that generalization is to be avoided insofar as specific structures are alleged to be *prima facie* obvious one from the other. *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985).

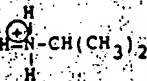
[1] On the basis of the record before us, we cannot sustain the Board's conclusion that the claimed salt and the diethanolamino salt disclosed by Richter are so "closely related in structure" as to render the former *prima facie* obvious in view of the latter. The claimed salt is a primary amine with an ether linkage. The diethanolamino salt disclosed by Richter is a secondary amine, without an ether linkage:



In addition, the only substituted ammonium salt of dicamba expressly disclosed by Richter having an ether linkage is the morpholino salt, which is *cyclic* in structure:



The claimed salt is, plainly, *acyclic*; i.e., linear. Lastly, while the isopropylamino salt disclosed by Richter is a primary amine, as is the claimed salt, its iso- structure is quite different:



[2] The lack of close similarity of structure is not negated by the fact that the

See generally Helmuth A. Wegner, "Prima Facie Obviousness of Chemical Compounds," 6 *Amer. Pat. L. Assoc. O. J.* 271 (1978).

claimed salt is a member of Richter's broadly disclosed genus of substituted ammonium salts of dicamba. The Solicitor contends that "[t]he relative size of the genus disclosed by the prior art would not appear to be a controlling factor in determining whether a *prima facie* case of obviousness exists for a species encompassed within the described genus," citing *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 806-09, 10 USPQ2d 1843, 1845-48 (Fed. Cir.), *cert. denied*, ___ U.S. ___, 110 S. Ct. 498 (1989). We decline to extract from *Merck* the rule that the Solicitor appears to suggest — that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it. In *Merck*, at issue on appeal was whether claims to a composition of two diuretics, amiloride and hydrochlorothiazide, present in a particular "medically synergistic" weight ratio, would have been obvious in view of a specific prior art disclosure of amiloride in combination with hydrochlorothiazide, one of 1200 such combinations disclosed in the prior art reference. *Id.* at 806, 10 USPQ2d at 1845. Based on the facts before it, including evidence at trial that the experimentation needed to arrive at the claimed dosage was "nothing more than routine," *Id.* at 809, 10 USPQ2d at 1847, the court affirmed the trial court's determination of obviousness. In contrast, though Richter discloses the potentially infinite genus of "substituted ammonium salts" of dicamba, and lists several such salts, the salt claimed here is not specifically disclosed. Nor, as we have explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it *prima facie* obvious. Every case, particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own facts.

[3] The Solicitor points out that, given the breadth of forms of dicamba (free acid, ester, or salt) disclosed by Richter as having herbicidal utility, one of ordinary skill in the art would appreciate that the dicamba group has significance with respect to imparting herbicidal activity to dicamba compounds. Thus, the Solicitor contends, one skilled in the art would have been motivated to use, with dicamba, substituted ammonium salts made from a known amine, such as the amine disclosed by Zorayan and Wideman, and would have expected such a salt to have herbicidal activity. Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some sug-

gestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). We see no such suggestion in Zorayan, which is directed to shampoo additives, nor in Wideman, which teaches that the amine used to make the claimed compound is a byproduct of the production of morpholine. Nor does the broad disclosure of Richter fill the gap, for the reasons discussed above.

Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed 2-(2-aminoethoxy) ethanol salt. *See Grabiak*, 769 F.2d at 731-32, 226 USPQ at 872 ("[I]n the case before us there must be adequate support in the prior art for the [prior art] ester/[claimed] thioester change in structure, in order to complete the PTO's *prima facie* case and shift the burden of going forward to the applicant."); *In re Lulu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.")

Conclusion

We conclude that the PTO did not establish a *prima facie* case of obviousness, and thus did not shift to Jones the burden of coming forward with unexpected results or other objective evidence of non-obviousness. Accordingly, the decision of the Board is

REVERSED.

District Court, S.D. New York

Lipton v. The Nature Co.

No. 91 Civ. 3007 (RO)

Decided January 16, 1992

COPYRIGHTS

Elements of copyright — Statutory elements — Originality (§205.0707)

Plaintiff's compilation of terms of "ven- which are collective terms relating to and hunting, is copyrightable, al- e terms are generally known and main, since many terms were

creatively interpreted from Middle English and therefore are products of plaintiff's imagination; and since arrangement of terms was original, reflecting plaintiff's consideration of factors such as fluidity of language and arrangement's lyrical and poetic potential.

2. Infringement pleading and practice — Jurisdiction (§217.05)

JUDICIAL PRACTICE AND PROCEDURE

Jurisdiction — Personal jurisdiction (§405.11)

Jurisdiction — Venue; transfer of action — In general (§405.1901)

Federal district court in New York has personal jurisdiction over non-resident who granted license to corporate defendant to manufacture and sell products on which are imprinted terms which allegedly infringe plaintiff's copyright, since claims arise from non-resident's contract to supply goods or services in New York, since claims allege commission by non-resident of tortious act outside New York which caused plaintiff injury within New York, and since non-resident should reasonably have expected that such action would have consequences within New York; venue in New York is proper, since copyright venue statute, 28 USC 1400(a), provides that venue is proper in district in which defendant "resides or may be found," and since defendant may be "found" in any district in which defendant is subject to personal jurisdiction.

Action by James Lipton against The Nature Co. and Michael Wein for copyright infringement. On defendants' motion to dismiss or to transfer. Motion denied.

Mark P. Ressler, of Kay Collyer & Boose, New York, N.Y., for plaintiff.

Noel M. Cook, of Owen Wickersham & Erickson, San Francisco, Calif.; Janet Dore, of Morgan & Finnegan, New York, and John P. Sutton, San Francisco, for defendants.

Owen, J.

Plaintiff James Lipton is an etymologist and author of the copyrighted book, *An Exaltation of Larks*, published originally in

1968, with expanded book at "terms of ing to na Nature C fendant I sells vario seventy-tl tudes"; th of ventry Wein has pilation c to Natur enty-two tion, Lip and arra substanti arranger that sev repeat t that app tion of l

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have treated only the failure of appellant to receive the letter, and not the alleged defects which led the board to hold the evidence inadmissible. However, appellant was entitled to have the "testimony" in the record before this court. Had we reached the other possible issues in this case, we might have found it necessary to consider the evidence in order to determine the propriety of the board's action.

Appellee additionally moved to correct diminution of the record and assess costs to appellant. Judge Baldwin granted the motion to augment the record and reserved the decision on assessment for the final decision in the case. In brief, appellee added the Patent Office notice setting testimony periods, appellant's notice of filing "Opposer's Record," the letter in controversy, appellee's motion to strike and responses thereto which led to the issuance of the show cause order, and appellant's petitions to the Commissioner and board, appellee's replies thereto, and the decisions rendered thereon. Twenty-two documents were added. Appellant opposed the motion to add these papers and assess costs, asserting they are unnecessary and were added solely to so financially burden appellant that "it will be impossible for the Opposer to proceed."

Recalling that the gist of this appeal as originally filed was the charge that appellant had been denied due process, it is evident that a complete record would have to include all the decisions by the Patent Office and the papers filed by the parties which occasioned those decisions. The impact of the letter of October 25, 1968, could not possibly be assessed without having it before us. Indeed, appellant would have been in a poor position to press his argument had the letter not been added by appellee. Compare *In re Locher*, 59 CCPA ___, 455 F.2d 1396, 173 USPQ 172 (1972). Similarly, the paper setting testimony periods had to be of record to even consider appellant's contention that his submission was timely. Finally, we think appellee was justified in adding the motion to strike and responses thereto since the arguments therein set the framework for the subsequent action by the board.

[2] The papers added to the record were those which should have been certified to the court in the first instance in order for us to fully consider the merits of this appeal. We therefore assess the cost of the entire addition to appellant. We realize that printing costs are expensive, but appellant is the party that initiated this appeal, and it must bear the financial burden the appeal imposes.

The decision of the Trademark Trial and Appeal Board is *affirmed*. Appellee's motion to assess the cost of correcting diminution of

the record to appellant is granted, and it is so ordered.

WORLEY, Chief Judge, took no part in the decision of this case.

Court of Customs and Patent Appeals

In re LINTNER

No. 8718

Decided May 4, 1972

PATENTS

1. Claims — Broad or narrow — In general (§20.201)

Claims broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter.

2. Patentability — Invention — In general (§51.501)

In determining propriety of Patent Office case for obviousness in the first instance, it is necessary to ascertain whether reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make proposed substitution, combination, or other modification.

3. Patentability — Invention — In general (§51.501)

Differences between applicant's and prior art's motivation for adding element to composition may be reflected in composition ultimately produced; claimed composition may possess unexpectedly superior properties or advantages as compared to prior art compositions; in this way, conclusion of prima facie obviousness may be rebutted and claimed subject matter ultimately held to be legally nonobvious.

Particular patents—Laundry Compositions

Lintner, Laundry Compositions, claims 1 to 5 of application refused.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Anthony E. Lintner, Serial No. 576,201, filed Aug 31, 1966; Patent Office Group 165. From decision re-

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jecting claims 1 to 5, applicant appeals. Af-
firmed.

EUGENE F. BUELL and BUELL, BLENKO &
ZIESENHEIM, both of Pittsburgh, Pa.; and
WILLIAM A. SMITH, JR., and SMITH, MI-
CHAEL, BRADFORD & GARDINER, both of
Arlington, Va., for appellant.

S. WM. COCHRAN (RAYMOND E. MARTIN of
counsel) for Commissioner of Patents.

Before RICH, ALMOND, BALDWIN, and LANE,
Associate Judges, and MALETZ, Judge,
United States Customs Court, sitting by
designation.

LANE, Judge.

This appeal was taken from the decision of
the Board of Appeals sustaining the rejection
of claims 1-5, all the claims in appellant's ap-
plication entitled "Laundry Compositions."¹
The rejection was based on 35 U.S.C. 103, the
examiner concluding that the claimed subject
matter would have been obvious to one of or-
dinary skill in the art. The board agreed, and
our review of the record and briefs reveals no
error in the board's decision. We accordingly
affirm.

The Invention

The claims are drawn to a laundry com-
position for use in a washing machine which is
a mixture of an organic cationic fabric softener,
such as an organic hydrazinium compound,
a sequestering phosphate which appar-
ently functions to soften the water intro-
duced into the washing machine, a sugar, an
optical brightener, and a water soluble non-
ionic organic dispersant of detergent which
may be a liquid or a solid. In the specification
of his application, appellant explains the
background and significance of the claimed
composition as follows:

Prior to the present invention no solid
composition including detergents, detergent
builders and fabric softeners was available.
Cationic fabric softeners were generally rec-
ognized as being incompatible with deter-
gents and detergent builders and had to be
added with the rinse water after detergents
had been removed with the wash water.
This practice was recognized to have many
disadvantages and to create special prob-
lems but no alternative was available. For
example, addition of fabric softeners in the
rinse eliminated the possibility of using
certain other desirable rinse additives as
well as tending to accumulate on the fabric
as a hydrophobic film which reduces ab-
sorbency and counteracts subsequent de-

tergent. The present invention eliminates
all these problems.

I have discovered a single laundry
composition which incorporates detergency,
water softening ability, fabric softening,
optical bleaching and at the same time
eliminates the problems created by the use
of a separate fabric softening in the rinse
cycle.

Claim 1 is illustrative of the five claims on
appeal and, subdivided for clarity, reads as
follows:

1. A laundry composition consisting by
weight essentially of
about 1% to 10% of a water soluble non-
ionic organic dispersant,
about 1% to 5% of an organic cationic
fabric softener,
about 15% to 30% of a sugar,
about 60% to 80% of a sequestering
phosphate, and
about 0.05% to 0.20% of an optical
brightener.

The Prior Art

The principal reference relied upon is the
patent to Germann² which discloses the use of
a cationic hydrazinium salt fabric softener in
conjunction with a nonionic detergent, phos-
phate, and optical brightener. The hydrazin-
ium cation was found to be compatible with
nonionic detergents and detergent builders,
such as phosphates, and in contrast to prior
softeners, it could be used in the wash cycle
along with other components of the laundry
composition. Rheiner et al.³ (Rheiner) dis-
closes a softening composition for application
to textiles which comprises a polyalkylene-
polyamine. In one example of the patent, glu-
cose is used in admixture with the amine so-
ftening agent. The publication of Speel et al.⁴
(Speel) discusses the use of cationic quaternary
ammonium compounds as fabric softeners and
teaches that sugars may be used in conjunction
with the cationic softening agent where "it is
desired to increase the actual weight of the
fabric while imparting a soft finish effect."

The Rejection

The examiner rejected claims 1-5 under 35
U.S.C. 103 as obvious from Rheiner and Speel
in view of Germann, additionally applying a
so-called "Arquads" publication to the rejec-
tion of claim 4. The latter reference is not in
the record certified to this court. However, the

² U.S. Patent No. 2,995,523 issued August 8,
1961.

³ U.S. Patent No. 2,243,980 issued June 3, 1941.

⁴ Speel et al., Textile Chemicals and Auxiliaries,
2d ed., pp. 390-91, Reinhold Publishing Corp., New
York (1957).

¹ Serial No. 576,201 filed August 31, 1966.

board did not discuss that "Arquads" publication, and the solicitor advises that reliance thereon is unnecessary. We accordingly give no further consideration to this publication. The board treated Germann as the primary reference and held the claims to be unpatentable under 35 U.S.C. 103 over Germann in view of Rheiner or Speel.

The board's decision is based on three findings. It was found that contrary to the factual assertion of appellant, he was not the first to utilize a cationic softener in conjunction with detergents and detergent builders. Germann solved the problems attendant the use of cationic softeners in the rinse cycle by utilizing a hydrazinium softener, an agent which is compatible with detergents and detergent builders. The board additionally found that the claims read on the hydrazinium softeners disclosed in Germann. Finally, the board held that the teachings in Rheiner and Speel to the effect that a sugar can be used in conjunction with cationic softeners render obvious the use of a sugar with Germann's hydrazinium softeners.

Opinion

[1] The sole issue before us is whether or not the claimed subject matter on appeal is obvious from the prior art relied upon within the meaning of 35 U.S.C. 103. The difference between Germann's composition and appellant's is the sugar employed by appellant. Although appellant urges that Germann's solution to the problem faced by appellant rests on the use of a limited class of cationic softeners, the board correctly observed that Germann's hydrazinium softeners are within the purview of all of the claims on appeal. Even were we to assume that the use of other cationic softeners would be nonobvious, the claims on appeal would nevertheless be unpatentable. Claims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter. *In re Mraz*, 59 CCPA ___, F.2d ___, 173 USPQ 25, 28 (1972). The question becomes whether or not the use of a sugar in the Germann composition would be obvious to one of ordinary skill in the art from Rheiner and Speel.

In Rheiner and Speel, the sugar is apparently used in conjunction with a cationic softener as a filler or weighting agent. The board seemingly held that the per se contemporaneous use of a cationic softener and a sugar is sufficient to suggest the contemporaneous use of a sugar and the specific softener disclosed in Germann. The solicitor contends that the admixture of sugar with a cationic softener to accomplish a filling or weighting function is

ample motivation to add a sugar to the Germann composition for the same purpose, and he argues that a prima facie case of obviousness of the claimed composition is thereby made out. The appellant's position is that the sugar is responsible for the compatibility of the cationic softener and the detergent and detergent builders and is therefore the key to the solution of the problem.⁵ Because neither Rheiner nor Speel recognize this attribute of sugar addition, they are insufficient, appellant concludes, to provide a basis for holding the claimed composition to be obvious.

[2] We agree with the solicitor that the composition herein claimed is prima facie obvious. In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed substitution, combination or other modification. In the present case, we are satisfied that Rheiner and Speel do suggest the use of a sugar with conventional laundry compositions such as that disclosed in Germann. The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be prima facie obvious from the purpose disclosed in the references.

[3] Differences between a patent applicant's and the prior art's motivation for adding an element to a composition may be reflected in the composition ultimately produced. A claimed composition may possess unexpectedly superior properties or advantages as compared to prior art compositions. In this way, the conclusion of prima facie obviousness may be rebutted and the claimed subject matter ultimately held to be legally nonobvious. However, in the present case we find no basis for disturbing the conclusion of obviousness. The result urged by appellant is the combination of a detergent, detergent builders and a cationic softener in a functional laundry composition thereby overcoming the various problems which arise when these sev-

⁵ It is not clear whether or not the solicitor challenges this factual assertion. The solicitor does argue that there is no competent evidence of record proving the superiority of appellant's composition over the prior art compositions relied upon and that there is no evidence sufficient to overcome the alleged prima facie case. The examples in appellant's specification do not appear to focus on the impact of the sugar on the effectiveness or operability of the claimed composition, and, indeed, Germann realizes the same result without using sugar. However, since our disposition of this case does not hinge on the accuracy of this contention, we proceed on the assumption that it is in fact correct.

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In re Doct

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eral ingredients are used separately in differ-
ent cycles of the laundering process. This is the
very result achieved by Germann without the
sugar. Accordingly, there is no departure from
the prior art in terms of the result achieved by
the addition of sugar, and the prima facie case
of obviousness has not been overcome.

The decision of the board sustaining the re-
jection of claims 1-5 under 35 U.S.C. 103 is
affirmed.

Patent Office Trademark Trial and Appeal Board

In re DOCUMENTOR SCIENCES CORPORATION

Decided Apr. 14, 1972

TRADEMARKS

1. Marks and names subject to owner- ship — Descriptive — Misdescrip- tive or not descriptive — Particu- lar marks (§67.5078)

"Documentor" is not merely descriptive as
applied to point-of-sale accounting machines.

Appeal from Examiner of Trademarks.

Application for registration of trademark of
Documentor Sciences Corporation, Serial No.
329,842. From decision refusing registration,
applicant appeals. Reversed.

SPENSLEY, HORN & LUBITZ, MARVIN JUBAS,
ROGER W. BLAKELY, JR., STANLEY W.
SOKOLOFF, MICHAEL A. PAINTER, EDWIN
H. TAYLOR, and OBLON, FISHER &
SPIVAK, all of Los Angeles, Calif., for ap-
plicant.

Before WALDSTREICHER, LEFKOWITZ, and
SHRYOCK, Members.

SHRYOCK, Member.

An application has been filed to register the
mark "DOCUMENTOR" for point-of-sale
accounting machines primarily designed for
use by the retail fast-food service industry
based upon computer principles designed to
read sales slips electronically, perform calcu-
lations, supply print-outs, record items of in-
ventory sold, and perform other functions.

Registration has been refused under the
provisions of Section 2(e) (1) of the Act on the
ground that "DOCUMENTOR" is merely
descriptive of applicant's goods.

The examiner takes the position that since
applicant's machines may document informa-
tion (supply proof of evidence) for the use of
others, a "documentor" is a name for such
machines. The examiner places his reliance on
a decision of the Commissioner of Patents
wherein "COMMUNICAT'R" was held
merely descriptive of electric dictating ma-
chines,¹ and on a definition of the word
document, as follows:

"An original or official paper relied upon
as the basis, proof, or support of anything
else;—in its broadest sense including any
writing, book, or other instrument convey-
ing information."² (Emphasis added by
examiner.)

We agree with applicant that the definition
relied upon by the Examiner of Trademarks
does not support his holding that the term in
question is merely descriptive of its machines.
The word "document" refers to a writing that
conveys information and in no sense is appli-
cant's accounting machine a writing or an in-
strument.³ While "DOCUMENTOR"
may, at best, suggest something relating to
some kind of document or documentation, it
takes either mental gymnastics or round about
reasoning to arrive at the conclusion that a
"DOCUMENTOR" is either the name for
applicant's goods or merely descriptive of the
function thereof. See: In re Check Savers, Inc.,
160 USPQ 561 (TT&A Bd., 1969); and cases
cited therein; and Ex parte Clary Corpora-
tion, 118 USPQ 168 (Comr., 1958). It is
noted that the latter decision, which held the
mark "TRANSACTOR" for sales registering
apparatus not merely descriptive thereof, was
rendered subsequent to the decision relied
upon by the examiner.

[1] It is concluded that the term
"DOCUMENTOR", as applied to appli-
cant's goods, is not merely descriptive.

Decision

The refusal to register is reversed.

¹ Ex parte Webster-Chicago Corporation, 105
USPQ 76 (1955).

² Webster's New Collegiate Dictionary, 1960.

³ Applicant states that in essence its product is an
electronic machine built to perform input, output
and processing functions.

The first question is: "Do you find that Hesston was the first to conceive the invention."

Now let me translate that question. . . . Translated, what that means is: Do you find by clear and convincing evidence that Hesston was the first to conceive the invention.

J. App. 3540-3544.

[3] Although these instructions do not explicitly require that the inventor's testimony on conception must be corroborated, they do instruct the jury to consider testimony or other pieces of evidence in light of all the evidence and to seek clear and convincing evidence of conception. In view of these instructions as a whole, and the evidence of record, we do not believe that the jury was confused on the issue of corroboration.

Second, the trial judge, in his November 1989 Supplemental Judgment Order, awarded Sperry one-half its attorney fees, based on Fed.R.Civ.P. 11 and 37(c), because New Idea wrongfully refused to admit certain facts during discovery. The judge further stated in that order:

Should the Court of Appeals agree with the defendants that they were not required to prove that Burkhart was the first to conceive the invention then, of course, 100 percent of the reasonable cost of proving the "Hesston facts" should be awarded.

New Idea Farm Equipment Corp. v. Sperry Corp., No. 84-C-10665, slip op. at 4 (N.D. Ill. November 6, 1989).

Sperry now contends that it was not necessary to prove Burkhart's conception, which New Idea should have admitted during discovery; Sperry therefore claims that it is entitled to the other half of its attorney fees. We disagree. An award of attorney fees under Rules 11 or 37 is subject to our review under an abuse of discretion standard. See *National Hockey League v. Metropolitan Hockey Club, Inc.*, 427 U.S. 639, 642, 96 S.Ct. 2778, 2780, 49 L.Ed.2d 747, 751 (1976). No such abuse was shown. Moreover, the outcome of the case could not have been nearly as clear at trial as hindsight might now indicate. Finally, proof of Burkhart's conception was relevant and necessary for Sperry to prevail. We see no abuse of the trial judge's discretion in not awarding the other half of the attorney fees to Sperry.

We have considered all the other points raised by New Idea, but find no reversible error.

III CONCLUSION

As indicated by its denial of New Idea's post-trial motions, the district court was not convinced by the record before the jury that a reasonable person could not have reached a verdict for Sperry or that the jury was misled. We are equally unpersuaded. New Idea has not convinced us that the jury's findings are not supported by substantial evidence, that those findings cannot support the legal conclusions drawn by the jury or the judge, or that the judge abused his discretion in denying New Idea's motion for a new trial or for JNOV. Therefore, the judgment is affirmed.

AFFIRMED

Court of Appeals, Federal Circuit

In re Mills

No. 90-1184

Decided October 9, 1990

PATENTS

1. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Apparatus which produces aerated cementitious composition by driving output pump for its mixing chamber at capacity greater than feed rate of ingredients into mixing chamber, and thereby drawing air into composition, is not obvious in view of prior patent for mixing apparatus, even though device of prior patent provides for regulation of flow rate into mixing chamber, since patent contains no suggestion or motivation for overdriving output pump so as to entrain air in mixed ingredients.

2. Patentability/Validity — Anticipation — In general (§115.0701)

Patentability/Validity — Obviousness — Relevant prior art — In general (§115.0903.01)

Board of Patent Appeals and Interferences erred by requiring applicant to show that prior art reference lacked functional characteristics of claimed device, since even though such requirement would be proper for rejection based on lack of novelty, it is not

III CONCLUSION

by its denial of New Idea's claims, the district court was not the record before the jury that person could not have reached a verdict or that the jury was mislead by substantial evidence, findings cannot support the legal conclusion by the jury or the judge, the judge abused his discretion in granting a new trial or otherwise, the judgment is

AFFIRMED

Appeals, Federal Circuit

In re Mills

No. 90-1184

October 9, 1990

Validity — Obviousness —
prior art — Particular inven-
tion (35 U.S.C. § 103)

which produces aerated cementitious composition by driving output pump means at capacity greater than the feed rate of the ingredients into mixing chamber by drawing air into mixing chamber in view of prior patent art, even though device of claim 6 for regulation of flow rate in mixing chamber, since patent claim 6 is not a motivation for overclaiming so as to entrain air in

Validity — Anticipation —
prior art (35 U.S.C. § 102)

Validity — Obviousness —
prior art — In general

Appeals and Interferences. In affirming applicant to show that the prior art lacked functional characteristics of the claimed device, since even if the prior art would be proper, lack of novelty, it is not

pertinent whether prior art device possesses claimed invention's functional characteristics if, as here, application was rejected on basis of obviousness and reference does not describe or suggest claimed invention's structure.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Peter S. Mills, serial no. 891,374, continuation of serial no. 607-805, filed May 4, 1984. From decision upholding examiner's rejection of claims 6-9 and 11-14, applicant appeals. Reversed.

James C. Wray, McLean, Va, for appellant.

Muriel E. Crawford, assistant solicitor (Fred E. McKelvey, solicitor, with her on brief), for appellee.

Before Miller, senior circuit judge, and Mayer and Lourie, circuit judges.

Lourie, J.

This appeal is from the November 2, 1989, decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences (Board), Appeal No. 88-0141, affirming the examiner's rejection, under 35 U.S.C. § 103, of claims 6-9 and 11-14 in Mills' application Serial No. 891,374, a continuation of Serial No. 607-805, filed May 4, 1984, entitled "Methods of and Apparatus for Producing Aerated Cementitious Compounds." The remainder of the claims (1-5, 10, and 15) have all been cancelled. We reverse.

I BACKGROUND

A. The Invention

Mills' claimed invention is an apparatus for producing aerated cementitious compositions. Claim 6 is the broadest claim:

6. Apparatus for producing an aerated cementitious composition, comprising
a mixing chamber being open to atmosphere and containing mixing means,
feed means for feeding ingredients comprising cement, foaming agent and liquid to the mixing chamber,

mixing means for mixing ingredients fed to the mixing chamber, pump means for pumping the mixed ingredients to a desired site and having a pump inlet connected to an outlet of the mixing chamber, drive motor means connected through gearbox means providing a pumping capacity of the pump means greater than the feed rate of the ingredients to the mixing chamber provided by the feed means, such that in operation air is drawn into the mixing chamber, and entrained in the mixed ingredients.

The essence of Mills' invention is the machine's ability to aerate a cementitious composition by driving the output pump at a capacity greater than the feed rate, thereby drawing air into the composition. This aeration produces a composition with substantially lower density than standard cementitious composition mixing ingredients.

B. The Reference

The sole reference upon which the Board relied in affirming the examiner's rejection was Mathis et al. U.S. Patent 4,117,547 (Mathis). Mathis discloses a mixing chamber which is open to the atmosphere and which contains a mixing means. Two feed means for feeding ingredients in the mixing chamber are provided. The first feed means may consist of a screw conveyor and the second, a flow metering device such as an adjustable valve. A pump means pumps the mixture from the mixing chamber to a desired site and a drive motor means is connected to mixing means and pump means. A separate motor drives the feed means.

A control system exists to arrest the feed means so as not to overfill the mixing chamber. This system comprises a level detector in the mixing chamber, which signals the feed means to close when the mixing chamber stores the predetermined maximum permissible quantity of material.

The examiner rejected the claims at issue under 35 U.S.C. § 103 as being unpatentable not only over Mathis but also in view of Gibson et al. U.S. Patent 2,717,770. However, the Board affirmed the examiner's rejection of claims 6-9 and 11-14 based solely on the Mathis reference. With regard to Gibson the Board stated:

We view the teachings of Gibson at best as being merely confirmatory of the fact that aerated mixtures can be produced by machines in which a pump means operates upon a mixing chamber at a greater rate than the ingredients are fed thereunto so that air is drawn into the mixing chamber and entrained in the mixed ingredients.

App. 2.

C. The Rejection

The Board affirmed the examiner's Section 103 rejection of claims 6-9 and 11-14, "finding correspondence in the Mathis reference for all of the subject matter recited in the appellants' claims. . . ." With regard to Mills' claim language relating to aerating the mixture, the Board stated: "[i]n our opinion, the differences between claim 6 and the Mathis machine . . . lie solely in the functional language of the claim." The Board further found that Mathis teaches the use of separate input and output motors in order to permit the various mixing means and pumps to operate at different rates, and that Mathis "contemplates a situation wherein the rate of the outlet pump would be greater than the inlet pumps. . . ." The Board concluded on this point: "[w]e are of the opinion that the Mathis machine is capable of being operated in such a fashion as to cause [the output] pump 18 to draw air into the mixing chamber 17 so that it is entrained in the mixture."

The Board also agreed with Mills' contention that Mathis is not directed to the problem of producing aerated cementitious material, but noted that Mills is not claiming a method, but an apparatus, and all of Mills' apparatus structure is present in the Mathis machine.

II DISCUSSION

All of the rejected claims are apparatus claims. The Board found "correspondence in the Mathis reference for all of the subject matter recited in appellants' claims" and that "[t]he Mathis machine discloses all of the structure set forth in claim 1" (a method claim not before us). It asserts that the use of such a mechanism would have been obvious and that the differences between claim 6 and the Mathis machine lie solely in the functional language of the claim, the preamble merely stating an intended use for the machine. This language suggests a lack of novelty rejection under 35 U.S.C. §102, rather than an obviousness rejection. However, no Section 102 rejection has been made or is before us. What is before us is a rejection for obviousness, and we must decide whether the Board erred in that rejection.

We note first that nonobviousness is a question of law to be determined from the facts. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). We review the Board's

determination of obviousness, based on the scope and content of the Mathis reference and the differences between the Mathis reference and the Mills claims, for correctness or error. *In re Carleton*, 599 F.2d 1021, 1024 n.14, 202 USPQ 165, 169 n.14 (CCPA 1979).

[1] After reviewing the record, the arguments in the briefs, and the Mathis reference, we conclude that Mathis would not have rendered the claimed invention obvious. The closest Mathis comes to suggesting Mills' claimed apparatus is at column 3, lines 42-47, which states

[T]he rate at which the inlet 2b receives a solid constituent depends on the speed of the feed screw 4. Such speed can be regulated by a prime mover 6 which includes a variable-speed transmission.

This brief reference contains no suggestion of "pump means and the feed means providing a pumping capacity of the pump means greater than the feed rate of ingredients to the mixing chamber provided by the feed means, such that in operation air is drawn into the mixing chamber, and air entrained in the mixed ingredients," as provided for in Mills' claim 6. While Mathis' apparatus may be capable of being modified to run the way Mills' apparatus is claimed, there must be a suggestion or motivation in the reference to do so. See *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification."). We see no such suggestion. The apparatus claimed by Mills is different from that of Mathis, since the fact that motor 6 of Mathis (the feed means) can be run at a variable speed does not require that motor 20 (connected to the pump) be run at a lesser speed "such that in operation air is drawn into the mixing chamber and air entrained in the mixed ingredients."

[2] The Board found that the difference between the claimed subject matter and the prior art resided solely in functional language and that appellant had to show that the prior art device lacked the functional characteristics of the claimed device, citing *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). *Ludtke*, however, dealt with a rejection for lack of novelty, in which case it was proper to require that a prior art reference cited as anticipating a claimed invention be shown to lack the characteristics of the claimed invention. That proof would in fact negate the assertion that the claimed invention was described in the prior art. We are here, however, facing an obvious-

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ness issue. It is not pertinent whether the prior art device possesses the functional characteristics of the claimed invention if the reference does not describe or suggest its structure. That is the case here. Given the facts before us, we hold that the Board was in error in affirming the examiner's rejection of claims 6-9 and 11-13 as obvious in view of Mathis, and we therefore reverse the Board.

REVERSED

mal and intended use, since "normal and intended use" of article includes period beginning after completion of manufacture or assembly and ending with article's ultimate destruction, loss, or disappearance, and since only facts of specific case will establish whether article's design can be observed during that period in such manner as to demonstrate ornamentality.

Court of Appeals, Federal Circuit

In re Webb

No. 90-1176

Decided October 11, 1990

PATENTS

1. Practice and procedure in Patent and Trademark Office — Board of Patent Appeals and Interferences — Rules and rules practice (§110.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Appealability (§410.4603)

Issue of whether design for hip prosthesis is functional is not properly before Court of Appeals for Federal Circuit, since examiner's final rejection of design patent application did not clearly specify functionality as ground for rejection, and since ground of functionality therefore cannot, by operation of 37 CFR 1.196(a), be incorporated into decision by Board of Patent Appeals and Interferences affirming rejection.

PATENTS

2. Patentability/Validity — Subject matter (§115.05)

Patentability/Validity — Design patents (§115.17)

Board of Patent Appeals and Interferences erred by holding that design for hip prosthesis is per se "functional," and therefore unpatentable, solely on ground that prosthesis is hidden from view during final stage of its useful life, since particular article's design cannot be presumed functional unless article is always concealed in its nor-

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Design patent application of John D. Webb, Jr., Roy Y. Hori, and George E. Simpson, serial no. 833,470. From decision upholding examiner's final rejection of sole claim in application, applicants appeal. Reversed and remanded.

Michael H. Baniak, of Willian, Brinks, Olds, Hofer, Gilson & Lione, Chicago, Ill. (Sandra A. Sellers, of Willian, Brinks, Olds, Hofer, Gilson & Lione, Washington, D.C., with him on brief), for appellant.

Nancy C. Slutter, associate solicitor (Fred E. McKelvey, solicitor, with her on brief), Arlington, Va., for appellee.

Before Archer, Plager, and Clevenger, circuit judges.

Clevenger, J.

This is an appeal from a decision of the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences ("Board") affirming the final rejection of the sole claim of appellants' ("Webb") U.S. Design Patent Application Serial No. 833,470. The claim for "[t]he ornamental design for a grooved femoral hip stem prosthesis as shown and described," was "rejected as being unpatentable under 35 U.S.C. §171 as being directed to non-statutory subject matter." The design can be appreciated from Figure 2 of the application reproduced below.

with notions of fair justice. Therefore, this exercise of personal defendants is appropriate of specific

consider defendants' his action under Fed. on the grounds that is district. The defense should be tried in of California, where ed declaratory judg-

is 28 U.S.C. § 1404, part:

ence of parties and rest of justice, a dis- er any civil action to r division where it ight:

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er 28 U.S.C. § 1404, rict of Louisiana is s. It is the site of the and principal place ocation of plaintiff's vant documents. In he headquarters and ess of OKI America, mp USA than is the tern District of Cali- that OKI America's hould not have been t should have been counterclaim in this the same issues that

a shift of the litiga- l be convenient only neys who represent ff argues that the ie first to file rule. -O-Two Fire Equip- 180 [92 USPQ 1]

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likely be the source of witnesses and documents, OKI America has an authorized distributor in California, and it has a California facility responsible for distribution of 30% of the supposedly infringing printers.

Finally, OKI America argues that the interests of justice would be served by transferring this case to California because then both cases would be tried in the same forum, which would ensure consistent judgments and would eliminate duplicate efforts by the parties and the two courts.

[2] This Court finds that this forum is more convenient than the Eastern District of California. The plaintiff is a resident of this forum; the defendants, located principally in New Jersey, can defend themselves as easily in Louisiana as in California.

Accordingly,

IT IS ORDERED that the motion of defendants, OKI America, Inc. and OKI-DATA, to dismiss plaintiff's complaint pursuant to Fed. R. Civ. P. 12(b)(2) and 12(b)(3) be and is hereby DENIED.

IT IS FURTHER ORDERED that the motion of OKI America, Inc. and OKI-DATA, to transfer this action to the Eastern District of California pursuant to 28 U.S.C. § 1404(a) be and is hereby DENIED.

IT IS FURTHER ORDERED that defendant Comp. USA's motion to stay the proceedings against it, in the event the case is severed and transferred, be and is hereby DENIED AS MOOT.

Court of Appeals, Federal Circuit

In re Rijckaert

No. 93-1206

Decided November 23, 1993

PATENTS

1. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Board of Patent Appeals and Interferences erred by affirming rejection, on grounds of obviousness, of claims for apparatus to record and reproduce electric signal on magnetic record carrier, since references relied upon to reject claims do not provide basis for prima facie determination of obviousness, in that prior art relied upon, either individually or when combined, does not disclose, suggest, or render obvious claimed invention, and since applicant's burden to rebut rejection of obviousness does not arise until prima facie case has been established.

tion of obviousness does not arise until prima facie case has been established.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 07/345,396, filed by Albert M.A. Rijckaert and Joannes A.E. Van Der Kop. From decision affirming final rejection of claims, applicants appeal. Reversed.

Edward W. Goodman (Algy Tamoshunas, with him on brief), Tarrytown, N.Y., for appellant.

Lee E. Barrett, associate solicitor, PTO (Fred E. McKelvey, solicitor, with him on brief), for appellee.

Before Lay, senior circuit judge (Eighth Circuit, sitting by designation), and Mayer and Lourie, circuit judges.

Lourie, J.

Albert Rijckaert and Joannes van der Kop ("Rijckaert") appeal from the decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences affirming the final rejection of claims 5-12, all of the pending claims in patent application serial no. 07/345,396, as being unpatentable under 35 U.S.C. § 103 (1988). Because the references relied upon to reject the claims do not provide the basis for a *prima facie* determination that the claimed invention would have been obvious, we reverse.

BACKGROUND

The patent application at issue relates to an apparatus for recording and reproducing an electric signal on a magnetic record carrier. Independent claim 11 is drawn to a recording apparatus and it specifies a relationship between time expansion or compression and three variables α , n , and M . Claim 11 reads, in pertinent part:

11. An apparatus for recording an electric signal on a magnetic record carrier in tracks which are inclined relative to the longitudinal direction of said record carrier, comprising:

[a] time-base correction circuit provid[ing] a time expansion or time compression of the signal blocks by a factor of $\alpha^n/(180*(M+1))$, where α is the wrap-

ping angle of the record carrier around the head drum and differs from 180° ; n is the number of head pairs, and M is the number of times within a specific time interval that a head pair which comes in contact with the record carrier during said time interval does not record a signal on the record carrier, said time interval being defined by those instants at which two consecutive track pairs are recorded by one or two head pairs.

Independent claim 12 is drawn to an apparatus for reproducing a recorded signal and it recites the reciprocal relationship between time compression or expansion and the three variables α , n , and M . Dependent claims 5-10 further limit claims 11 or 12.

The Board upheld the final rejection of claims 5 and 7-12 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 4,757,392 to Awamoto in view of Driessen et al., *An Experimental Digital Video Recording System*, CE-32 I.E.E.E. Transactions on Consumer Electronics 3, Aug. 1986, at 362-70. The Board also upheld the final rejection of claim 6 as being unpatentable over Awamoto and Driessen in view of U.S. Patent 4,542,417 to Ohta.

DISCUSSION

We review *de novo* the Board's ultimate determination of obviousness. *In re De Blauwe*, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984). Underlying factual inquiries, such as the scope and content of the prior art, differences between the prior art and the claimed invention, and level of ordinary skill in the art are reviewed for clear error. *See In re Caveney*, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed. Cir. 1985).

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). If the examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

All of the claims except claim 6 stand rejected under 35 U.S.C. § 103 as being obvious over Awamoto in view of Driessen.¹ Awamoto, the primary reference, discloses a signal processing circuit for a video recording and reproducing apparatus. Awamoto specifically discloses the time expansion of an input signal by a factor of two and the corresponding time compression of an output signal in a manner inverse to that of the time expansion. Further, Awamoto uses two video heads mounted on a rotary drum "of any of a well known video tape loading mechanism such that [the heads] follow parallel tracks skewed relative to the length of video tape." Driessen discloses a recording system using two pairs of heads mounted on piezo-ceramic actuators.

The Board concluded that the subject matter of the claims would have been obvious over Awamoto in view of Driessen, stating that "the time expansion or time compression relationship is satisfied for the expansion of two disclosed [in] Awamoto when a wrapping angle of 360° , one pair of heads and no non-recording intervals are assumed." The Board further asserted that the recognition of the claimed relationship between time expansion/compression and the three variables α , n , and M is "the mere discovery of a relationship that is applicable to [a] prior art apparatus[, and] does not [give] rise to a patentable invention." Thus, in affirming the rejection, the Board first assumed that the claim limitation at issue, the relationship between time expansion/compression and the three variables, was somehow "inherent" in the prior art as shown by Awamoto. The Board also assumed specific values for the claimed variables in order to assert that Awamoto's device satisfies the claimed relationship.

[1] Rijckaert argues that the examiner has not established a *prima facie* case of obviousness and that the examiner's assumptions do not constitute the disclosure of prior art. We agree. Awamoto does not disclose the wrapping angle of the record carrier around the head drum or the number of times that a head pair, which comes in contact with the record carrier does not record a signal on the record carrier. Nor does Awamoto discuss the claimed relationship of the three varia-

¹ The claims stand or fall together since no separate argument for patentability has been made for each claim.

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sen, the secondary reference, is relied upon
only to teach the provision of a pair of write
beads having a mechanically rigid coupling
to each other and does not remedy the defi-
ciencies of Awamoto. Thus, the prior art
relied upon does not disclose, suggest, or
render obvious the claimed invention, either
individually or when combined.³

Awamoto does not describe the use of time
expansion and compression as a means of
optimally filling tracks, much less suggest
that the three variables of the claims are
even a factor in determining the amount of
time expansion or time compression. Rather,
Awamoto is concerned primarily with pro-
cessing a high-quality broadcast television
signal for use in conventional video machin-
ery, and with compensating for errors intro-
duced to such a signal by a transfer circuit.
The Commissioner's assertion "that" the
[analysis discussed in his brief] and Awa-
moto demonstrate that the relationship was,
in fact, well known in the art" is unavailing.
While the court appreciates the Commis-
sioner's thorough explanation of the claimed
relationship in his brief, the Commissioner's
brief is not prior art. The prior art is Awa-
moto, and it does not indicate that the rela-
tionship is well known in the art nor does it
suggest the claimed relationship. See *In re*
Yates, 663 F.2d 1054, 211 USPQ 1149, 1151
(CCPA 1981) (when the PTO asserts that
there is an explicit or implicit teaching or
suggestion in the prior art, it must indicate
where such a teaching or suggestion appears
in the reference).

To support the Board's affirmance of the
rejection, the Commissioner points out that

The Commissioner admits that other limita-
tions recited in claims 11 and 12 are not found in
Awamoto; however, those limitations were not
argued before the Board or this court. Thus, we
agree with the Commissioner that those limita-
tions are not at issue here.

The Board also noted that the claims are
not "specific" in that they claim the three vari-
ables as a "factor" of the expansion or compres-
sion time. The Board stated, "claims 11 and 12
fail to say which of expansion time or compres-
sion time is factored by the variables, how or
when one of the two times is selected based on the
variables or how each of the two times is related
to the variables." The Board further stated, "the
relationship is probably satisfied by any prior art
video tape recording and reproducing apparatus
that otherwise satisfies the remaining require-
ments of the claims at bar." While the Board's
position implies a possible rejection based upon
35 U.S.C. § 112, this issue is not before us. In
any event, the statement that the relationship is
"probably satisfied" by the prior art is specula-
tive and therefore does not establish a *prima facie*
case of unpatentability.

in the recording art, the exact matching of
signal time to recording time is an optimal
condition, and that this condition would be
met by fulfilling the claimed relationship.
While the condition described may be an
optimal one, it is not "inherent" in Awa-
moto. Nor are the means to achieve this
optimal condition disclosed by Awamoto, ex-
plicitly or implicitly. "The mere fact that a
certain thing may result from a given set of
circumstances is not sufficient [to establish
inherency.]" *In re Oelrich*, 666 F.2d 578#
581-82, 212 USPQ 323, 326 (CCPA 1981)
(citations omitted) (emphasis added). "That
which may be inherent is not necessarily
known. Obviousness cannot be predicated on
what is unknown." *In re Spormann*, 363
F.2d 444, 448, 150 USPQ 449, 452 (CCPA
1966). Such a retrospective view of inher-
ency is not a substitute for some teaching or
suggestion supporting an obviousness rejection.
See *In re Newell*, 891 F.2d 899, 901, 13
USPQ2d 1248, 1250 (Fed. Cir. 1989).

Rijckaert also argues that the rejection of
dependent claim 6 as being obvious over
Awamoto and Driessen in view of Ohta is
improper. Ohta discloses an apparatus for
compensating for signal loss in a single-head
video recorder using a time compression fac-
tor of 3/5 (a signal of time period 5t/4 is
compressed into a track of time period 3t/4)
so that a signal is recorded completely during
the time period that it takes the recording
head to scan the magnetic tape. Regarding
the Ohta patent, the examiner stated, "Ohta
was only relied upon to support the idea that
other compression factors are used in the
prior art." The relationship between
the time expansion/compression and the
three variables recited in the claims from
which claim 6 depends, which is absent in the
combination of Awamoto and Driessen, is
not supplied by Ohta. Thus, we agree that
the rejection of claim 6 under § 103 is im-
proper for the reasons set forth above with
respect to the other claims.

While the Commissioner criticizes Rijck-
aert's arguments regarding the § 103 rejec-
tions, the burden to rebut a rejection of
obviousness does not arise until a *prima facie*
case has been established. In the case before
us, it was not.

CONCLUSION

The decision of the United States Patent
and Trademark Office Board of Patent Ap-

The Board did not specifically address the
rejection of claim 6; therefore, claim 6 was con-
sidered to be affirmed for the reasons stated by
the examiner. See 37 C.F.R. § 1.196(a) (1993).

peals and Interferences affirming the final rejection is reversed.

REVERSED

District Court, N.D. Illinois

Rasmussen v. The West Inc.

No. 92 C 8495

Decided June 29, 1993

JUDICIAL PRACTICE AND PROCEDURE

1. Jurisdiction — Personal jurisdiction (§405.11)

Federal district court in Illinois has personal jurisdiction, in copyright infringement action, over Arizona corporation that does no business in Illinois, since defendant purposefully and knowingly initiated two purchases of allegedly infringed needlepoint design from Illinois resident, since design was created and copyrighted by that resident, sent from Illinois, and included copyright notice which warned defendant that infringement could subject it to suit in Illinois, since complaint stems directly from defendant's purchases, and since defendant therefore had minimum contacts with state sufficient to satisfy requirements for due process.

2. Jurisdiction — Venue; transfer of action — In general (§405.1901)

Transfer of copyright infringement action from Illinois to Arizona is not warranted, since there is no evidence that defendant will incur greater hardship litigating in Illinois than plaintiff would suffer pursuing claim in Arizona, since Illinois is more convenient forum for two of three presently-known witnesses, and since interests of justice do not favor either forum, in that there is no related litigation pending in Arizona nor any complex state law issue to be decided.

Action by Susan Rae Rasmussen against The West Inc., for copyright infringement. On defendant's motions to dismiss for lack of personal jurisdiction, or to transfer action to Arizona. Both motions denied.

David C. Brezina and Dennis M. McWilliams, of Lee, Mann, Smith, McWilliams, Sweeney & Ohlson, Chicago, Ill., for plaintiff.

Eric L. Samore, of Querrey & Harrow, Chicago, for defendant.

Aspen, J.

Plaintiff Susan Rae Rasmussen ("Rasmussen") brings this copyright infringement action against defendant The West, Inc. ("West"). Presently before us is West's motion to dismiss this action for lack of personal jurisdiction and its motion, in the alternative, to transfer this action to Arizona. For the following reasons, we deny both of defendant's motions.

I. Factual Background

Plaintiff Rasmussen, an Illinois resident, is the sole proprietor of Sular Designs, and earns her income, in part, by designing, publishing, and selling needlepoint patterns. In March, 1990, Rasmussen received a copyright for her "Fleur Du Quad" needlepoint design, chart, and instructions.

West is a non-profit Arizona corporation. With two paid employees and a group of volunteers, West runs a needlepoint and embroidery shop, selling supplies and giving lessons to its customers. All of West's profits are donated to needy women and children. The corporation does not maintain an office in Illinois, nor does it have any employees, officers, directors, or other representatives in Illinois. West does not advertise or solicit business in this state, does not own or rent any property here, or list a local phone number. In short, West conducts all of its business within Arizona.

In September, 1991, West mail-ordered, *inter alia*, several copies of the Fleur Du Quad pattern from Rasmussen. One year later in September, 1992, West again mail-ordered the copyrighted pattern from Rasmussen. Both times, Rasmussen received the orders and payment in Illinois and sent the patterns to West in Arizona. Both times, the patterns contained a Notice of Copyright.

Rasmussen alleges that one of West's agents photocopied the Fleur Du Quad design and instructions and sold at least two of the photocopies in violation of the copyright. Peggy Wolfe ("Wolfe"), a resident of Green Bay, Wisconsin, purportedly witnessed a West representative selling copies of the Fleur Du Quad design in a park in Tucson. At the time, Wolfe was with a group of five other needlepointers working together on patterns in the park.

II. Discussion

A. Motion to Dismiss

West seeks to dismiss this suit, arguing that its contacts with Illinois are too insub-

For the purposes of this motion, we will take the complaint's well-pleaded allegations as true, as well as all reasonable inferences therefrom.

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June 22, 1983. These two papers, filed before decision, deal only with the printing of the Combined Appendix of ten volumes said to contain a total of 9,307 pages, 5,743 of which were designated by appellee after appellants had initially designated the balance. There is an excessively detailed dispute over how many of the pages designated by appellee were necessary. Appellee appears not to have contributed to the cost of printing the appendix, which cost, paid by appellants, is said to have been \$31,850.15. Federal Rule of Appellate Procedure (FRAP) 30(b) authorizes us to impose upon a party the cost of printing material "unnecessarily" included. FRAP Rule 39(a) provides that, in the absence of an order by the court, in the case of a reversal "costs shall be taxed against the appellee."

Having considered the foregoing, we have a clear appreciation of the impossibility of determining, within reason, exactly what was or was not necessarily included in the appendix in this extended and complex litigation. We conclude that, under all of the circumstances with which we have necessarily become familiar in deciding this case, it is fair and equitable that the parties share equally the cost of printing the Combined Appendix and that otherwise each party bear its own costs. In accordance with Rule 39(a), it is so ordered.

Reversed and Remanded.

Miller, Circuit Judge, concurring in part.

Although I agree with the majority's analysis and holding on the fraud issue, it seems appropriate to state my conclusion that, because of the unpredictability of propanil in 1957, the district court erred in granting R&H an April 4, 1957, date of conception rather than a date concurrent with a reduction to practice, in the summer of 1957 — after the May 27, 1957, date of filing of Monsanto's application, so that the Monsanto patent constitutes a 35 U.S.C. §102(e) bar to the R&H patent. *Alpert v. Slatin*, 305 F.2d 891, 896, 134 USPQ 296, 301 (CCPA 1962).

Court of Appeals, Federal Circuit

W.L. Gore & Associates, Inc.
v. Garlock, Inc.

Nos. 83-613/614

Decided Nov. 14, 1983

PATENTS

1. Court of Appeals for the Federal Circuit — Weight given decision reviewed (\$26.59)

Parties' argument relating to salutary injunction of FRCivP 52(a) cannot be controlling on all issues, where dispositive legal error occurred in interpretation and application of patent statute, 35 USC.

2. Court of Appeals for the Federal Circuit — Weight given decision reviewed (\$26.59)

Findings that rest on erroneous view of law may be set aside on that basis.

3. Construction of specification and claims — Claim defines invention (\$22.30)

Claims measure and define invention.

4. Construction of specification and claims — Combination claims (\$22.35)

Infringement — Process patents (\$39.65)

Court's restriction of claimed multi-step process to one step constitutes error, whether done at behest of patentee relying on that restriction to establish infringement by one who employs only that one step in process otherwise distinct, or at behest of accused infringer relying on that restriction to establish invalidity by showing that one step in prior art process otherwise distinct; invention must be considered as whole.

5. Court of Appeals for the Federal Circuit — Weight given decision reviewed (\$26.59)

CAFC is not at liberty to substitute its own for district court's findings underlying district court's conclusion that claim is invalid.

6. Patentability — Anticipation — Process (\$51.225)

It is irrelevant that those using invention may not have appreciated results where patent owner's operation of device is consistent, reproducible use of claimed invention; were that alone enough to prevent anticipation; it would be possible to obtain patent for old and unchanged process.

7. Use and sale — Extent and character of use (§69.5)

Nonsecret use of claimed process in usual course of producing articles for commercial purposes is public use.

8. Use and sale — Extent and character of use (§69.5)

Patentees' commercialization of product produced by its patented process can result in forfeiture of patent granted them for that process on application filed by them more than one year later; however, their secret commercialization of process cannot be bar to patent grant on that process.

9. Patent grant — Intent of patent laws (§50.15)

Early public disclosure is linchpin of patent system.

10. Interference — Priority (§41.70)

Law disfavors prior inventor who benefits from process by selling its product but suppresses, conceals, or otherwise keeps process from public, as against later inventor who promptly files patent application from which public will gain disclosure of process.

11. Patentability — Evidence of — In general (§51.451)

District court that in its consideration of prior art disregarded unpredictability and unique nature of product to which claimed inventions relate errs.

12. Construction of specification and claims — By prior art (§22.20)

District court that in its consideration of prior art considers claims in less than their entireties errs.

13. Patentability — Evidence of — Suggestions of prior art (§51.469)

District court that considers references in less than their entireties, i.e., in disregarding disclosures in references that diverge from and teach away from invention at hand, errs.

14. Construction of specification and claims — Comparison with other claims (§22.40)

Claims must be considered individually and separately.

15. Patentability — Anticipation — Combining references (§51.205)

There must have been something present in teachings in references to suggest to one skilled in art that claimed invention before court would have been obvious.

16. Patentability — Evidence of — Suggestions of prior art (§51.469)

Fact that patentee proceeded, contrary to accepted wisdom of prior art is strong evidence of nonobviousness.

17. Patentability — Tests of — Skill of art (§51.707)

Imbuing one of ordinary skill in art with knowledge of invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to insidious effect of hindsight syndrome wherein that which only inventor taught is used against its teacher.

18. Patentability — Invention — In general (§51.501)**Patentability — Tests of — Skill of art (§51.707)**

Decisionmaker must forget what he or she has been taught at trial about claimed invention and cast mind back to time invention was made to occupy mind of one skilled in art who is presented only with references, and who is normally guided by then-accepted wisdom in art.

19. Pleading and practice in courts — Burden of proof — Validity (§53.138)**Presumption for patent grant — Patent Office consideration of prior art (§55.5)**

It is not law that presumption of validity is weakened greatly where Patent Office has failed to consider pertinent prior art; presumption has no separate evidentiary value; it cautions decisionmaker against rush to conclude invalidity; submission of additional art that is merely "pertinent" does not dispel that caution; however, inescapable burden of persuasion on one who would prove invalidity remains throughout trial.

20. Pleading and practice in courts — Burden of proof — Validity (§53.138)**Presumption from patent grant — Patent Office consideration of prior art (§55.5)**

Burden of proving invalidity may be facilitated by prior art that is more pertinent than that considered by PTO.

21. Patentability — Evidence of — In general (§51.451)

District court that specifically declines to consider objective evidence of nonobviousness errs; that evidence can often serve as insur-

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hindsight when confronted with difficult task
of evaluating prior art; even when prior art
evidence points more in direction of nonob-
viousness than obviousness; objective evidence
may tend to reassure decisionmaker.

22. Patentability — Anticipation — In general (§51.201)

Anticipation requires disclosure in single
prior art reference of each element of claim
under consideration.

23. Patentability — Anticipation — Process (§51.225)

Patentability — Composition of matter (§51.30)

Anticipation of inventions set forth in prod-
uct claims cannot be predicated on mere con-
jecture respecting characteristics of products
that might result from practice of processes
disclosed in references.

24. Patentability — Anticipation — Infringement as test (§51.211)

Accused infringer's employment of process
of dominating patent is not anticipation of
invention described and claimed in improve-
ment patent.

25. Patentability — Anticipation — In general (§51.201)

Patentability — Invention — In general (§51.501)

Inherency and obviousness are distinct
concepts.

26. Patentability — Evidence of — In general (§51.451)

All evidence bearing on obviousness issue,
as with any other issue raised in conduct of
judicial process, must be considered and eval-
uated before required legal conclusion is
reached.

27. Patentability — Evidence of — In general (§51.451)

Objective evidence of nonobviousness; i.e.,
"indicia" of *Graham v. John Deere Co.*, 148
USPQ 459, may in given case be entitled to
more weight or less, depending on its nature
and its relationship to invention's merits; it
may be most pertinent, probative, and reveal-
ing evidence available to aid in reaching con-
clusion on obvious/nonobvious issue.

28. Patentability — Evidence of — Commercial success — In general (§51.4551)

Praise greeting products claimed in patent
from suppliers, including owner of prior art

patent, is objective evidence of
nonobviousness.

29. Patentability — Composition of matter (§51.30)

Claim to new product is not required to
include critical limitations.

30. Specification — Sufficiency of disclosure (§62.7)

Patents are written to enable those skilled
in art to practice invention, not public, and
Section 112 speaks as of application filing
date, not as of time of trial.

31. Specification — Sufficiency of disclosure (§62.7)

Section 112 requires that inventor set forth
best mode of practicing invention known to
him at time application was filed.

32. Claims — Indefinite — In general (§20.551)

Use of "stretching at rate exceeding specific
percent per second" in claims is not
indefinite.

33. Claims — Specification must support (§20.85)

It is claimed invention for which enable-
ment is required.

34. Specification — Sufficiency of disclosure (§62.7)

Patent is not invalid merely because some
experimentation is needed; patent is invalid
only when those skilled in art are required to
engage in undue experimentation to practice
invention.

35. Construction of specification and claims — Claim defines invention (§22.30)

Distinguishing what infringes from what
does not is role of claims, not of specification.

36. Construction of specification and claims — Defining terms (§22.45)

Patent applicant can be his own
lexicographer.

37. Defenses — Fraud (§30.05)

Fraud must be shown by clear and con-
vincing evidence; state of mind of one making
representations is most important of elements
to be considered in determining existence of
fraud; good faith and subjective intent, while
they are to be considered, should not neces-
sarily be made controlling; under ordinary
circumstances, fact of misrepresentation coup-

led with proof that party making it had knowledge of its falsity is enough to warrant drawing inference that there was fraudulent intent; where public policy demands complete and accurate disclosure it may suffice to show nothing more than that misrepresentations were made in atmosphere of gross negligence as to their truth.

38. Pleading and practice in courts — Issues determined — Validity and infringement (§§3.505)

Better practice is for district court to decide both validity and infringement issues when both are contested at trial, enabling conduct of single appeal and disposition of entire case in single appellate opinion.

39. Infringement — Tests of — Comparison with claim (§§3.803)

Infringement is decided with respect to each asserted claim as separate entity.

Particular patents — Porous Products

3,953,566, Gore, Process for Producing Porous Products, holding of invalidity of claims 3 and 19 reversed and of claims 1 and 17 affirmed.

4,187,390, Gore, Porous Products and Process Therefor, holding of invalidity reversed.

Appeal from District Court for the Northern District of Ohio, Manos, J.; 220 USPQ 220.

Consolidated actions by W. L. Gore & Associates, Inc., against Garlock, Inc., for patent infringement, in which defendant counterclaims for declaratory judgment of patent invalidity, noninfringement, fraudulent solicitation, and entitlement to attorney fees. From judgment for defendant, plaintiff appeals and defendant cross-appeals. Affirmed in part, reversed in part, and remanded; Davis, Circuit Judge, concurring in result in part and dissenting in part, with opinion.

David H. Pfeffer, New York, N.Y. (J. Robert Dailey and Janet Dore, both of New York, N.Y., and John S. Campbell, Newark, Del., of counsel) for appellant.

John J. Mackiewicz, Philadelphia, Pa. (Dale M. Heist, Philadelphia, Pa., on the brief, Bernard Ouziel, New York, N.Y., of counsel) for appellee.

Before Markey, Chief Judge, and Davis and Miller, Circuit Judges.

Markey, Chief Judge.

Appeal from a judgment of the District Court for the Northern District of Ohio holding U.S. Patents 3,953,566 ('566) and 4,187,390 ('390) invalid. We affirm in part, reverse in part, and remand for a determination of the infringement issue.

Background

Tape of unsintered polytetrafluorethylene (PTFE) (known by the trademark TEFLON of E. I. du Pont de Nemours, Inc.) had been stretched in small increments. W. L. Gore & Associates, Inc. (Gore), assignee of the patents in suit, experienced a tape breakage problem in the operation of its "401" tape stretching machine. Dr. Robert Gore, Vice President of Gore, developed the invention disclosed and claimed in the '566 and '390 patents in the course of his effort to solve that problem. The 401 machine was disclosed and claimed in Gore's U.S. Patent 3,664,915 ('915) and was the invention of Wilbert L. Gore, Dr. Gore's father. PTFE tape had been sold as thread seal tape, i.e., tape used to keep pipe joints from leaking. The '915 patent, the application for which was filed on October 3, 1969, makes no reference to stretch rate, at 10% per second or otherwise, or to matrix tensile strength in excess of 7,300 psi.

Dr. Gore experimented with heating and stretching of highly crystalline PTFE rods. Despite slow, careful stretching, the rods broke when stretched a relatively small amount. Conventional wisdom in the art taught that breakage could be avoided only by slowing the stretch rate or by decreasing the crystallinity. In late October 1969, Dr. Gore discovered, contrary to that teaching, that stretching the rods as fast as possible enabled him to stretch them to more than ten times their original length with no breakage. Further, though the rod was thus greatly lengthened, its diameter remained virtually unchanged throughout its length. The rapid stretching also transformed the hard, shiny rods into rods of a soft, flexible material.

Gore developed several PTFE products by rapidly stretching highly crystalline PTFE, including: (1) porous film for filters and laminates; (2) fabric laminates of PTFE film bonded to fabric to produce a remarkable material having the contradictory properties of impermeability to liquid water and permeability to water vapor, the material being used to make "breathable" rainwear and filters; (3) porous yarn for weaving and braiding into other products, like space suits and pump packing; (4) tubes used as replacements for human arteries and veins; and (5) insulation for high performance electric cables.

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On May 21, 1970, Gore filed the patent application that resulted in the patents in suit. The '566 patent has 24 claims directed to processes for stretching highly crystalline, unsintered, PTFE. The processes, inter alia, include the steps of stretching PTFE at a rate above 10% per second and at a temperature between about 35°C and the crystalline melt point of PTFE. The '390 patent has 77 claims directed to various products obtained by processes of the '566 patent.

It is effectively undisputed that the present inventions filled a long sought yet unfilled need. The United States Army and the research director of a Garlock Inc. (Garlock) customer had been looking for and following up every remote lead to a waterproof/breathable material for many years.

It is undisputed that the present inventions enjoyed prompt and remarkable commercial success due to their merits and not to advertising or other extraneous causes.

It is undisputed that the inventions provide the most important synthetic material available for use in vascular surgery, hundreds of thousands of persons having received artificial arteries formed of the patented products since 1976, and that the patented products have unique properties useful in other medical procedures, in communications satellites, radar systems, and electrical applications.

It is undisputed that the major sources of PTFE, ICI and du Pont, greeted the patented products as "magical," "bewitching," "a remarkable new material," and one that "differs from other processed forms of Teflon."

It is undisputed that the patented products were met with skepticism and disbelief by at least one scientist who had worked with PTFE at du Pont for many years and who testified as an expert at trial.

It is undisputed that Garlock first produced an accused product in response to a customer's request for a substitute for the patented product, that Garlock advertised its accused product as a "new form" of PTFE and as "a versatile new material which provides new orders of performance for consumer, industrial, medical and electrical applications," and that the customer describes that accused product as "a new dimension in rainproof/breathable fabrics."

Proceedings

On Nov. 2, 1979, Gore sued Garlock for infringement of process claims 3 and 19 of the '566 patent, and sought injunctive relief, damages and attorney fees. Garlock counterclaimed on Dec. 18, 1979, for a declaratory judgment of patent invalidity, non-infringe-

ment, fraudulent solicitation, and entitlement to attorney fees. On Feb. 7, 1980, Gore filed a second suit for infringement of product claims 14, 18, 36, 43, 67 and 77 of the '390 patent. In light of a stipulation, the district court consolidated the two suits for trial.

Gore alleged infringement of certain claims by certain products:

'566 patent claims	'390 patent claims	Garlock Product
19	14, 43	film
--	36, 77	laminated
19	18	yarn
--	67	braided packing
3	--	tape

At trial, Garlock addressed only claims 1, 3, 17, and 19 of the '566 patent and claims 1, 9, 12, 14, 18, 35, 36, 43, 67 and 77 of the '390 patent. See Appendix to this opinion.

The district court, in a thorough memorandum accompanying its judgment, and in respect of the '566 patent: (1) found claim 1 anticipated under 35 U.S.C. §102(a) by Gore's use of its 401 machine and use by the Budd Company (Budd) of a Cropper machine; (2) declared all claims of the patent invalid under 102(b) because the invention had been in public use and on sale more than one year before Gore's patent application, as evidenced by Budd's use of the Cropper machine; (3) held claims 1, 3, 17 and 19 invalid for obviousness under 35 U.S.C. §103, on the basis of various reference pairings: (a) Japanese patent 13560/67 (Sumitomo) with U.S. patent 3,214,503 (Markwood); (b) U.S. patent 2,776,465 (Smith) with Markwood; or (c) Gore's '915 patent with Sumitomo; and (4) held all claims invalid as indefinite under 35 U.S.C. §112.

35 U.S.C. §102(a) and (b) provide:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or ***
35 U.S.C. §103 provides:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In its opinion respecting the '390 patent, the district court held: (1) claims 1, 9, 12, 14, 18, 35, 36, 43, 67 and 77 invalid §§102 and 103 in view of Sumitomo and Smith; and (2) all claims invalid as indefinite under §112.

The court found that Gore did not commit fraud before the Patent and Trademark Office (PTO), denied Garlock's request for attorney fees, and refrained from deciding the infringement issue.

Issues

Did the district court err in: (1) its holding of invalidity under §§102(a), 102(b), 103 and 112; (2) its finding that Gore did not commit fraud on the PTO; or (3) denying attorney fees.

Opinion

This hard fought and bitterly contested case involved over two years of discovery, five weeks of trial, the testimony of 35 witnesses (19 live, 16 by deposition), and over 300 exhibits. The district court issued an exhaustive 37-page memorandum opinion reflective of a careful, conscientious approach to the determination of the many issues presented at trial.

The record on appeal consists of 2000 pages. The parties' briefs total 199 pages. In those briefs, counsel repeatedly accuse each other of numerous and serious breaches of the duty of candor owed the court. Each cites instances in which the testimony, the findings, and the record are or are said to be quoted in part and out of context. As a result, the usefulness and reliability of the briefs as means of informing the court has been greatly diminished if not destroyed, and careful, time-consuming study of all exhibits and each page of the record has been required.

35 U.S.C. §112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.

Appellant cited 80 prior court opinions in its main brief. Appellee's brief totally ignores all but two of those citations, but adds 57 more. Appellant's reply brief cites 126 prior court opinions, 34 earlier cited, 67 newly cited, and 25 of those cited by appellee. Appellee's reply brief cites 17 prior court opinions, 4 earlier cited, 7 newly cited, and 6 of the 147 cited by appellant. Accordingly, 211 prior court opinions have been evaluated in relation to the proof found in the record.

In light of the entire record and the applicable law, we are convinced that Garlock failed to carry its burden of proving all claims of the present patents invalid.

Standard of Review

[1,2] Where, as here, dispositive legal error occurred in interpretation and application of the patent statute, 35 U.S.C., the parties' arguments relating to the salutary injunction of Fed. Rule Civ. P. 52(a) cannot be controlling on all issues. Though findings that "rest on an erroneous view of the law may be set aside on that basis," *Pullman-Standard v. Swint*, 456 U.S. 273 (1982), it is unnecessary here to set aside any probative fact found by the district court or to engage in what would be an inappropriate reweighing of the facts.

Among the legal errors extant in the record, each of which is discussed below, are (1) the invention set forth in each claim was not in each instance considered as a whole; (2) 35 U.S.C. §102(b) was applied though criteria for its application were not present; (3) the references were not assessed in their entireties; (4) an inherency theory under §§102 and 103 was inappropriately applied; (5) that which only the inventor taught was attributed to the prior art; (6) individual steps in prior art processes dealing with materials distinct from those with which the present inventions dealt were erroneously equated to steps in the claimed processes; (7) objective evidence of nonobviousness was disregarded; and (8) the function and application of §112 were misconstrued.

Because it permeated so much of the district court's analysis, we note more fully its frequent restriction of its consideration to 10% per second rate of stretching, which it called the "thrust of the invention." That approach is repeated throughout. Garlock's briefs, which refer repeatedly to the "thrust of the invention," to "the inventive concept," and to the claims "shorn of their extraneous limitations." That facile focusing on the "thrust," "concept," and "shorn" claims, resulted in treating the claims at many points as though they read differently from those actually allowed and in suit.

[3] It is true that Dr. Gore emphasized rapid stretching, for example, as well as the amount of stretch and other process limitations, during prosecution of the application for the '566 patent. Yet it is the claims that measure and define the invention. *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339, 128 USPQ 354 (1961); *Bowser, Inc. v. U.S.*, 388 F.2d 346, 349, 156 USPQ 406, 409 (Ct. Cl. 1967).

[4] Each claimed invention must be considered as a whole. 35 U.S.C. §103; *Schenck, A.G. v. Nortron Corp.*, 218 USPQ 698, 700 (Fed. Cir. 1983). In determining obviousness, there is "no legally recognizable or protected 'essential,' 'gist,' or 'heart' of the invention." *Aro*, 365 U.S. at 345. A court's restriction of a claimed multi-step process to one step constitutes error, whether done at the behest of a patentee relying on that restriction to establish infringement by one who employs only that one step in a process otherwise distinct, or at the behest of an accused infringer relying on that restriction to establish invalidity by showing that one step in a prior art process otherwise distinct.

(1) Invalidity

(a) '566 Patent

(i) §102(a) and The 401 Machine

It is undisputed that the district court held only claim 1 of the '566 patent to have been anticipated under §102(a) by operation of the 401 machine in the Gore shop before Dr. Gore's invention in late October 1969. It did so on the deposition testimony of two former Gore employees, documents, and drawings of the 401 machine.

In August 1969, Gore offered to sell to Export Tool Company (Export) tape "to be made" on the 401 machine. Tape made on the 401 machine was shipped to Export on October 24, 1969. The trial judge found the rolls on the 401 machine were, at least at some point in time before October 1969, spaced less than four feet apart and that the rate of stretch accomplished in operating that machine (admittedly operated in accord with the description of machine operation in the '915 patent) must have been greater than 10% per second. The district court credited testimony that Teflon 6-c, a highly crystalline form of Teflon, was used because it was the standard resin at the time, and that the tape was stretched at a temperature above 35°C. Thus it cannot be said that the record fails to support the district court's finding that the

limitations of claim 1 were met by Gore's operation of the 401 machine before Dr. Gore's asserted "late October 1969" date of invention. Though he was working with the operation of the 401 machine, Dr. Gore offered no proof that his invention date was before the date of shipment to Export.

[5] Gore, seeking a review here of the evidence, points to certain inadequacies as indicating a failure to meet the required clear and convincing standard under §102(a). At the time of trial, the district court, bound by precedent then applicable, applied a preponderance of the evidence test. Gore asserts, erroneously, that the clearly erroneous standard does not therefore apply on this appeal. Gore does not, however, point to any basis on which the district court's findings must be held to have been clearly erroneous under the clear and convincing standard. We are not at liberty, of course, to substitute our own for the district court's findings underlying its conclusion that claim 1 is invalid.

[6] Gore's operation of the 401 machine must thus be viewed as a consistent, reproducible use of Dr. Gore's invention as set forth in claim 1, and it is therefore irrelevant that those using the invention may not have appreciated the results. *General Electric Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 248, 67 USPQ 155, 157-58 (1945). Were that alone enough to prevent anticipation, it would be possible to obtain a patent for an old and unchanged process. *Ansonia Brass & Copper Co. v. Electric Supply Co.*, 144 U.S. 11, 18 (1892); see, *H.K. Regar & Sons, Inc. v. Scott & Williams, Inc.*, 63 F.2d 229, 231, 17 USPQ 81, 83 (2d Cir. 1933).

[7] The nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use. *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 20, 41 USPQ 155, 161 (1939), and there was no evidence that any different process was used to produce the articles shipped to Export.

Thus it cannot be said that the district court erred in determining that the invention set forth in claim 1 of '566 patent was known or used by others under §102(a), as evidenced by Gore's operation of the 401 machine before Dr. Gore's asserted date of that invention.

In view of our affirmance of the judgment reached on claim 1 under 102(a), we need not discuss other asserted grounds of invalidity of claim 1. There was, however, no evidence whatever that the inventions set forth in other claims, of either the '566 or the '390 patent, were known or used by others as a result of Gore's operation of the 401 machine before late October 1969.

(ii) §102(b) and the Cropper Machine

In 1966 John W. Cropper (Cropper) of New Zealand developed and constructed a machine for producing stretched and unstretched PTFE thread seal tape. In 1967, Cropper sent a letter to a company in Massachusetts, offering to sell his machine, describing its operation, and enclosing a photo. Nothing came of that letter. There is no evidence and no finding that the present inventions thereby became known or used in this country.

In 1968, Cropper sold his machine to Budd, which at some point thereafter used it to produce and sell PTFE thread seal tape. The sales agreement between Cropper and Budd provided:

ARTICLE "E" - PROTECTION OF TRADE SECRETS Etc.

1. BUDD agrees that while this agreement is in force it will not reproduce any copies of the said apparatus without the express written permission of Cropper nor will it divulge to any person or persons other than its own employees or employees of its affiliated corporations any of the said know-how, or any details whatsoever relating to the apparatus.

2. BUDD agrees to take all proper steps to ensure that its employees observe the terms of Article "E" 1 and further agrees that whenever it is proper to do so it will take legal action in a Court of competent jurisdiction to enforce any one or more of the legal or equitable remedies available to a trade secret plaintiff.

Budd told its employees the Cropper machine was confidential and required them to sign confidentiality agreements. Budd otherwise treated the Cropper machine like its other manufacturing equipment.

A former Budd employee said Budd made no effort to keep the secret. That Budd did not keep the machine hidden from employees legally bound to keep their knowledge confidential does not evidence a failure to maintain the secret. Similarly, that du Pont employees were shown the machine to see if they could help increase its speed does not itself establish a breach of the secrecy agreement. There is no evidence of when that viewing occurred. There is no evidence that a viewer of the machine could thereby learn anything of which process, among all possible processes, the machine is being used to practice. As Cropper testified, looking at the machine in operation does not reveal whether it is stretching, and if so, at what speed. Nor does looking disclose whether the crystallinity and temperature elements of the invention set

forth in the claims are involved. There is no evidence that Budd's secret use of the Cropper machine made knowledge of the claimed process accessible to the public.

The district court held all claims of the '566 patent invalid under 102(b), supra, note 3, because "the invention" was "in public use [and] on sale" by Budd more than one year before Gore's application for patent. Beyond a failure to consider each of the claims independently, 35 U.S.C. §282; *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 487, 24 USPQ 308 (1935), and a failure of proof that the claimed inventions as a whole were practiced by Budd before the critical May 21, 1969 date, it was error to hold that Budd's activity with the Cropper machine, as above indicated, was a "public" use of the processes claimed in the '566 patent, that activity having been secret, not public.

Assuming, arguendo, that Budd sold tape produced on the Cropper machine before October 1969, and that that tape was made by a process set forth in a claim of the '566 patent, the issue under §102(b) is whether that sale would defeat Dr. Gore's right to a patent on the process inventions set forth in the claims.

[8] If Budd offered and sold anything, it was only tape, not whatever process was used in producing it. Neither party contends, and there was no evidence, that the public could learn the claimed process by examining the tape. If Budd and Cropper commercialized the tape, that could result in a forfeiture of a patent granted them for their process on an application filed by them more than a year later. *D.L. Auld Co. v. Chroma Graphics Corp.*, No. 83-585, slip op. at 5-6 (Fed. Cir. Aug. 15, 1983); See *Metalizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 68 USPQ 54 (2d Cir. 1946). There is no reason or statutory basis, however, on which Budd's and Cropper's secret commercialization of a process, if established, could be held a bar to the grant of a patent to Gore on that process.

[9,10] Early public disclosure is a linchpin of the patent system. As between a prior inventor who benefits from a process by selling its product but suppresses, conceals, or otherwise keeps the process from the public, and a later inventor who promptly files a patent application from which the public will gain a disclosure of the process, the law favors the latter. See *Horwath v. Lee*, 564 F.2d 948, 195 USPQ 701 (CCPA 1977). The district court therefore erred as a matter of law in applying the statute and in its determination that Budd's secret use of the Cropper machine and sale of tape rendered all process

ed. There is no use of the Cropper of the claimed ic.

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claims of the '566 patent invalid under §102(b).

(iii) §103

In considering claims 1, 3, 17, and 19 of the '566 patent, the district court recognized that analysis of the obviousness issue under §103 requires determination of the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

[11,12,13] In its consideration of the prior art, however, the district court erred in not taking into account the import of the markedly different behavior of PTFE from that of conventional thermoplastic polymers clearly established and undisputed on the record, and in thus disregarding the unpredictability and unique nature of the unsintered PTFE to which the claimed inventions relate. In *re* Whiton, 420 F.2d 1082, 164 USPQ 455 (CCPA 1970); in considering claims in less than their entireties, *Schenck, supra*; and in considering the references in less than their entireties, i.e., in disregarding disclosures in the references that diverge from and teach away from the invention at hand. In *re* Kuderma, 426 F.2d 385, 165 USPQ 575 (CCPA 1970).

Invalidity of claim 1 under §102(a) having been determined, it is unnecessary to discuss in detail the applicability of §103 to that claim. If claim 1 had not been held anticipated under §102(a) in light of operation of the 401 machine, it is clear from the discussion here that claim 1 could not properly have been held invalid under §103.

Claim 3 depends from and thus incorporates claim 1 but specifies a rate of stretch of 100% per second. Claim 17 also depends from claim 1 and specifies an amount of stretch of about twice the original length. Claim 19 depends from claim 17 but specifies an amount of stretch of about five times the original length.

U.S. patent 2,983,961 to Titterton, Volume 13 of the *Encyclopedia of Polymer Science and Technology* (1970), the Sumitomo patent, and witnesses for both parties, establish that teachings related to conventional thermoplastic polymers are inapplicable to PTFE.

Articles by Dogliotti and Yelland, *Effect of Strain Rate on the Viscoelastic Properties of High Polymeric Fibrous Materials*, 4 *High Speed Testing* 211 (1964) and Robinson and Graham, *Methods of Characterization of Polymeric Materials by High Speed Testing Techniques*, 5 *High Speed Testing* 261

(1965), teach that conventional plastics and sintered PTFE can be stretched further if stretched slowly. Dr. Gore demonstrated at trial and at oral argument before us that an attempt to stretch highly crystalline, unsintered PTFE slowly results in breakage, and that rapid stretching produces a greatly lengthened rod of soft, flexible material.

The '566 patent contains an example of stretching an article to 16 times its length. Smith and the '915 patent teach that PTFE could not be stretched beyond four times its length without heating it to above its crystalline melt temperature, a step avoided by Dr. Gore and as set forth in the claims.

Sumitomo teaches that there is a length limit to stretching unsintered PTFE, and does not suggest what that limit might be. Markwood, U.S. patent 3,208,100 to Nash (Nash), and U.S. patent 2,823,421 to Scarlett (Scarlett) teach that *non-PTFE* thermoplastics can be stretched rapidly and to extended lengths, and also teach reduction, elimination, or avoidance of crystallinity before stretching.

The disclosure in the Smith and '915 patents that a PTFE article may be stretched to as much as four times its length encompasses the step of stretching to twice its length set forth in claim 17 and establishes that such step would have been obvious.

[14] Claims 3 and 19 must be considered individually and separately. 35 U.S.C. §282. Nowhere, in any of the references, is it taught or suggested that highly crystalline, unsintered PTFE could be stretched at a rate of about 100% per second as required by asserted claim 3. Nor is it anywhere suggested that by rapid stretching a PTFE article be stretched to more than five times its original length as required by asserted claim 19. On the contrary, the art as a whole teaches the other way.

[15] In concluding that obviousness was established by the teachings in various pairs of references, the district court lost sight of the principle that there must have been something present in those teachings to suggest to one skilled in the art that the claimed invention before the court would have been obvious. In *re* Bergel, 292 F.2d 955, 956-57, 130 USPQ 206, 208 (CCPA 1961); In *re* Sponnoble, 405 F.2d 578, 585, 160 USPQ 237, 244 (CCPA 1969).

The court's pairing of Sumitomo and Markwood disregarded, as above indicated, the undisputed evidence that the unsintered PTFE of Sumitomo does not respond to the conventional plastics processing of Markwood and the art recognition of that fact. Whiton, *supra*, 420 F.2d at 1085, 164 USPQ at 457. In evaluating claim 19, for example, the pairing disregarded Sumitomo's limited

length of stretch teaching. In evaluating claim 3, the court recognized that Sumitomo made no mention of rate of stretch. Looking to Markwood to supply that teaching disregarded not only the conventional plastics-unsintered PTFE distinction but also the clear divergence of Markwood's teaching that crystallinity must be reduced or avoided from the presence of "highly crystalline" in all claims of the '566 patent.

Similarly, and for many of the same reasons, the pairing of Markwood's and Smith's teachings was an inappropriate basis for concluding that the processes set forth in claims 3 and 19 would have been obvious. As above indicated, Markwood's rapid stretching of conventional plastic polypropylene with reduced crystallinity would not suggest rapid stretching of highly crystalline PTFE, in light of teachings in the art that PTFE should be stretched slowly. The Smith patent is owned by du Pont, where Dr. Gore's process invention was considered to have produced a "remarkable new material." That circumstance is not surprising, for Smith, though dealing with PTFE, says not a word about any rate of stretch.

Lastly, the pairing of Sumitomo and the '915 patent suffers from the same shortcomings. The pairing resulted from a hypothetical set forth in Garlock's post trial brief, and was based on no testimony or other evidence in the record. In respect to claim 3, neither reference mentions rate of stretch or suggests its importance. In respect of claim 19 both references point away from the claimed invention in their limited length-of-stretch teachings. The '915 patent states: "the 65 percent expanded material could be expanded a second time for an additional 65 percent expansion or a total length increase ratio of 1:2.72 [less than three times the original length]. However, great care was necessary to obtain a uniformly expanded material at these very great expansion ratios." Thus the '915 patent suggests that the amount of stretch of 500% set forth in claim 19 (more than five times the original length) is not possible.

As indicated, Sumitomo and Smith are totally silent respecting the rate of stretch, and there is simply no teaching in the art that would suggest to one of ordinary skill that Markwood's fast stretching of other thermoplastics could or should be employed in the process of treating PTFE taught by either Sumitomo or Smith. Indeed, Smith not only says nothing about rate of stretch, its preferred teaching is away from other elements of the inventions set forth in claims 3 and 19 Smith discloses that stretching should be done after the PTFE is heated above its crystalline

melting point and with decreased crystallinity. Smith teaches:

Below about 300°C it is *not possible* to draw more than about 4X [times] and while such draw ratios can be attained around 300°C and below the polymer's crystalline melting point with resultant orientation and improved properties it is preferred to use temperatures at or above the polymer's crystalline melting point. (Emphasis added).

Nash teaches that the film should be plasticized, i.e., made more viscous, before stretching. Contrary to that teaching, Dr. Gore did not reduce crystallinity before increasing the rate of stretch, but maintained the unsintered PTFE "highly crystalline" while stretching at a 100% per second rate and to more than five times, as set forth respectively in claims 3 and 19.

[16] On the entire record and in view of all the references, each in its entirety, it is clear that a person of ordinary skill confronted with a PTFE tape breakage problem would have either slowed the rate of stretching or increased the temperature to decrease the crystallinity. Dr. Gore did neither. He proceeded contrary to the accepted wisdom of the prior art by dramatically increasing the rate and length of stretch and retaining crystallinity. That fact is strong evidence of nonobviousness. *United States v. Adams*, 383 U.S. 39 (1966).

Having learned the details of Dr. Gore's invention, the district court found it within the skill of the art to stretch other material rapidly (Markwood); to stretch PTFE to increase porosity (Sumitomo); and to stretch at high temperatures (Smith). The result is that the claims were used as a frame, and individual, naked parts of separate prior art references were employed as a mosaic to recreate a facsimile of the claimed invention. At no point did the district court, nor does Garlock, explain why that mosaic would have been obvious to one skilled in the art in 1969, or what there was in the prior art that would have caused those skilled in the art to disregard the teachings there found against making just such a mosaic. On the contrary, the references and the uncontested testimony, as above indicated, established that PTFE is *sui generis*. It is not surprising, therefore, that, unlike the situation in *Stratoflex, Inc. v. Aeroquip Corp.*, 218 USPQ 871 (Fed. Cir. 1983), there was no testimony and no finding that one skilled in the art would transfer conventional thermoplastic processes to those for unsintered PTFE, or would have been able to predict what would happen if they did.

[17] To imbue one of ordinary skill in the art with knowledge of the invention in suit,

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when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

[18] It is difficult but necessary that the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art. Had that been here done the inventions set forth in the claims 3 and 19 of the '566 patent could only have been held non-obvious to those skilled in the art at the time those claimed inventions were made.

[19] Error in visualizing the burden of proof on obviousness may have contributed to the court's application here of the prior art. Adopting the phrase from earlier precedents, the court said "the presumption [of validity] is weakened greatly where the Patent Office has failed to consider pertinent prior art." That is not the law of established precedent in this court. *SSIH Equipment S.A. v. ITC*, 218 USPQ 678, 687 (Fed. Cir. 1983); *Solder Removal Co. v. ITC*, 582 F.2d 628, 633, 199 USPQ 129, 133, n. 9 (CCPA 1978). The presumption has no separate evidentiary value. It cautions the decisionmaker against a rush to conclude invalidity. Submission of additional art that is merely "pertinent" does not dispel that caution. It is difficult to imagine a patent law suit in which an accused infringer is unable to add some new "pertinent" art. The inescapable burden of persuasion on one who would prove invalidity, however, remains throughout the trial. 35 U.S.C. §282.

[20] The burden of proving invalidity may of course be facilitated by prior art that is *more pertinent* than that considered by the PTO. That did not happen here. In the present case, Sumitomo, Smith, and the '915 patent were among references considered by the PTO. Other references referred to as not considered were merely cumulative, disclosing nothing not disclosed in references that were considered by the PTO. The Canadian counterpart of Nash was considered by the PTO. The relevant disclosures of Markwood appear in Sandiford patent 3,544,671 and Paratheon patent 3,637,906; both considered by the PTO. The Russian Author's Certificate 240,997, assuming its status as prior art and whatever the material with which it dealt, contributed nothing beyond the teachings of the '915 patent considered by the PTO.

[21] As discussed more fully below, the district court erred in specifically declining to

consider the objective evidence of nonobviousness. In *re Sernaker*, 702 F.2d 989, 996, 217 USPQ 1, 7 (Fed. Cir. 1983). That evidence can often serve as insurance against the insidious attraction of the siren hindsight when confronted with a difficult task of evaluating the prior art. Though the prior art evidence here pointed more in the direction of nonobviousness than obviousness, the objective evidence may tend, as it did in *Sernaker*, supra, to reassure the decisionmaker.

In sum, the district court erred as a matter of law on this record in concluding that Garlock had met its burden of proving that the inventions of claims 3 and 19 of the '566 patent would have been obvious.

(b) '390 patent

(i) §102

The district court found product claims 1, 9, 12, 14, 18 and 43 inherently anticipated because it found that the microstructure of nodes interconnected by fibrils is an inherent characteristic of paste-extruded PTFE products resulting from the process disclosed in Smith. The court found the first four of those claims and claim 43, plus claims 35, 36, 67 and 77 inherently anticipated because high strength PTFE products are inherent in the examples of Sumitomo.

The teachings of Smith include neither a disclosure nor a suggestion of "porous" products having a "microstructure characterized by nodes interconnected by fibrils" as required by the claims found to have been anticipated by Smith.

The teachings of Sumitomo do not include a disclosure of products having "a matrix tensile strength *** above about 7,300 psi" as required by the claims found to have been anticipated by Sumitomo.

[22] Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *Soundscrubber Corp. v. U.S.*, 360 F.2d 954, 960, 148 USPQ 298, 301, adopted, 149 USPQ 640 (Ct. Cl. 1966). Neither Smith nor Sumitomo disclose an invention set forth in any claim of the '390 patent.

The incongruity in findings that the different processes of Smith and Sumitomo each inherently produced identical products is striking.

Garlock attempted with expert testimony to overcome the prior art shortcomings as proof of anticipation. Gore rebutted with its own expert testimony. It is unnecessary, however, to resolve apparent conflicts in the divergent testimony, much if not all of which took

the form of pure unsupported assertion. No inter partes tests in which the Smith and Sumitomo processes were conducted are of record. No products of those processes were placed in evidence, and there was, of course, no analysis of any such evidentiary products.

Nor is it necessary to evaluate the inappropriate disparagement in Garlock's brief of Dr. Sperati as a "friend" of Gore.

[23] Given the unique nature of unsintered PTFE, we are not persuaded that the "effect" of the processes disclosed in Smith and Sumitomo, an "effect" undisclosed in those patents, would be always to inherently produce or be seen always to produce products meeting all of the claim limitations. Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references. In re Felton, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973). It is clear that the teachings of neither Smith nor Sumitomo place the products claimed in the '390 patent in possession of the public.

The teachings of Smith and Sumitomo are so unacceptably vague concerning characteristics of products produced by their respective processes as not to support an anticipation rejection. That fact is confirmed by the PTO's having fully considered those references and by its having issued the '390 patent over them.

[24] Garlock's assertion that it employs a process covered by the Smith patent, if true, is irrelevant. The '390 patent was allowed over Smith as a reference. Assuming Smith is a dominating patent, the rule of law is clear that an accused infringer's employment of the process of a dominating patent does not render that employment an anticipation of an invention described and claimed in an improvement patent. As indicated, there is no present record basis for finding that the Smith process in itself necessarily and inherently results in the products, each considered in its entirety, in the claims of the '390 patent. The testimony of Garlock's expert about ex parte tests, the records of which he destroyed before trial, cannot serve as such a basis. The effusive praise of Dr. Gore's claimed products by the owner of the Smith patented process would appear, on the contrary, to confirm the action of the PTO in issuing the '390 patent.

Garlock has not met its burden of showing that claims 1, 9, 12, 14, 18, and 43 are anticipated by Smith or that claims 1, 9, 12, 14, 35, 36, 43, 67, and 77 are anticipated by Sumitomo.

(ii) §103

[25] The scope and content of the prior art and level of ordinary skill, discussed above in relation to the '566 patent, would be the same for the '390 patent. The district court did not, however, nor does Garlock, apply the Graham criteria, supra, to the '390 claims, apparently assuming that the claimed products, having been found inherent in the processes of Sumitomo and Smith, would have been obvious in view of those references. If so, that was error. Inherency and obviousness are distinct concepts. In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966).

In discussing inherency the district court did recognize differences between Smith's disclosure and the inventions set forth in claims 1, 9, 12, 14, 18, and 43, i.e., the absence from Smith of a description of the products of Smith's process as porous and the absence from Smith of a disclosure that those products have a microstructure characterized by nodes interconnected by fibrils.

Similarly, a difference between Sumitomo's disclosure and the inventions set forth in claims 1, 9, 12, 14, 35, 36, 43, 67, and 77 was recognized in the absence from Sumitomo of a quantification of the matrix tensile strengths of the products of Sumitomo's process. The district court also discussed differences between the dependent claims and the prior art. Because we conclude that the independent claims of the '390 patent are patentable over the art of record, we need not discuss the dependent claims.

[26] Having determined that the invention would have been obvious in view of the process of either Smith or Sumitomo, the district court did not discuss the strong showing of objective evidence of nonobviousness here present, saying with respect to one part of such evidence, "no amount of commercial success can save it." That approach was error. All evidence bearing on the issue of obviousness, as with any other issue raised in the conduct of the judicial process, must be considered and evaluated before the required legal conclusion is reached. *Stratoflex*, supra, 218 USPQ at 879.

[27] The objective evidence of nonobviousness, i.e., the "indicia" of Graham, supra, may in a given case be entitled to more weight or less, depending on its nature and its relationship to the merits of the invention. It may be the most pertinent, probative, and revealing evidence available to aid in reaching a conclusion on the obvious/nonobvious issue. It should when present always be considered as an integral part of the analysis.

Gore's fabric laminates, for example, as set forth in claims 36 and 77, satisfied a long-felt

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need for a material having the contradictory properties of being simultaneously breathable (allowing water vapor or perspiration to pass) and waterproof. The record establishes that such a material had long been sought by makers of rainwear and outerwear, and by the U.S. Army as well. That Gore's fabric laminates filled that need is attested by the rise in their annual dollar sales from zero to seven million in the first five years of their availability.

Gore's PTFE tubes for replacement of human arteries and veins, also satisfied a long-felt need. The uncontradicted evidence establishes that Gore's PTFE tubes hold blood without leaking, need not be pre-clotted with the patient's blood, are chemically inert, and, being breathable, are less likely to cause an air embolism. The value and uniqueness of those four properties make Gore's PTFE tubes, as described in unchallenged testimony, "the most important synthetic material presently existing" in vascular surgery, and, along with other evidence in the record, reflect the intended working of the patent system.

As discussed above, current annual sales of over sixty million dollars are attributable to the merits of the products claimed in the '390 patent. Considering the long-felt need for those products and the obvious commercial advantage to be gained by meeting that need, it is reasonable to conclude that the claimed products of the '390 patent would not have been obvious to persons of ordinary skill in the art at the time the claimed inventions were made.

[28] As above indicated, the praise which greeted the products claimed in the '390 patent from PTFE suppliers, including the owner of the Smith patent, is further objective evidence of nonobviousness.

[29] Garlock's appeal argument that the '390 claims are invalid because the recited minimum matrix tensile strengths are not "critical" is without merit. A claim to a new product is not legally required to include critical limitations. In re Miller, 441 F.2d 689, 696, 169 USPQ 597, 602 (CCPA 1971). The '390 claims are not drawn to optimization of ingredients or ranges within broad prior art teachings, but to new porous PTFE products of particular characteristics.

In sum, and in view of the difficulty of working with unsintered PTFE and its unpredictable response to various processing techniques, the vagueness of Smith and Sumitomo concerning the products produced by those processes, the filling of at least two long-felt needs and the commercial success described above, we conclude that the inventions set forth in claims 1, 9, 12, 14, 18, 35, 36, 43, 67, and 77 of the '390 patent would

not have been obvious to those skilled in the art at the time those inventions were made.

(c) §112 and the '566 and '390 patents

The patents in suit resulted from a single application and thus have substantially identical specifications. The holding of invalidity on the basis of §112 is common to both patents.

The district court found that the patents did not disclose sufficient information to enable a person of ordinary skill in the art to make and use the invention, as required by §112, first paragraph, and that certain claim language was indefinite, presumably in light of §112, second paragraph, because: (1) there was no definition in the specification of "stretch rate," different formulae for computing stretch rate having been developed and presented at trial; (2) there was no way taught in the specification to calculate the minimum rate of stretch above 35°C; (3) the phrase "matrix tensile strength" is indefinite; and (4) the phrase "specific gravity of the solid polymer" is indefinite.

[30] The findings rest on a misinterpretation of §112, its function and purpose. The district court considered whether certain terms would have been enabling to the public and looked to formula developments and publications occurring well after Dr. Gore's filing date in reaching its conclusions under §112. Patents, however, are written to enable those skilled in the art to practice the invention, not the public. In re Storrs, 245 F.2d 474, 478, 114 USPQ 293, 296-97 (CCPA 1957), and §112 speaks as of the application filing date, not as of the time of trial. In re Mott, 539 F.2d 1291, 1296, 190 USPQ 536, 541 (CCPA 1976). There was no evidence and no finding that those skilled in the art would have found the specification non-enabling or the claim language indefinite on May 21, 1970, when the application which resulted in issuance of Dr. Gore's patents was filed. Indeed, the expert quoted by the district court and whose testimony was primarily relied upon respecting formulae, was still in school at that time.

There is uncontradicted evidence in the record that at the time the application was filed "stretch rate" meant to those skilled in the art the percent of stretch divided by the time of stretching, and that the latter was measurable, for example, with a stopwatch. Concern for the absence from the specification of a formula for calculating stretch rate is therefore misplaced, and the post-filing date development of varying formulae, including Dr. Gore's later addition of a formula in his corresponding Japanese patent, is irrelevant.

[31] Section 112 requires that the inventor set forth the best mode of practicing the invention known to him at the time the application was filed. Calculating stretch rate at that time was accomplished by actually measuring the time required to stretch the PTFE material. That was the only mode then used by the inventor, and it worked. The record establishes that calculation by that mode would have been employed by those of ordinary skill in the art at the time the application was filed. As indicated, Dr. Gore's disclosure must be examined for §112 compliance in light of knowledge extant in the art on his application filing date.

[32] The district court, though discussing enablement, spoke also of indefiniteness of "stretch rate," a matter having to do with §112, second paragraph, and relevant in assessment of infringement. The use of "stretching * * * at a rate exceeding about 10% per second" in the claims is not indefinite. Infringement is clearly assessable through use of a stopwatch. No witness said that could not be done. As above indicated, subsequently developed and therefore irrelevant formulae cannot be used to render non-enabling or indefinite that which was enabling and definite at the time the application was filed.

[33] Similarly, absence from the specification of a method for calculating the minimum rate of stretch above 35°C does not render the specification non-enabling. The specification discloses that "[t]he lower limit of expansion rates interact with temperature in a roughly logarithmic fashion, being much higher at higher temperatures." Calculation of minimum stretch rate above 35°C is nowhere in the claims, and it is the *claimed* invention for which enablement is required. The claims require stretching at a rate greater than 10% per second at temperatures between 35°C and the crystalline melt point of unsintered PTFE. That the minimum rate of stretch may increase with temperature does not render non-enabling Dr. Gore's specification, particularly in the absence of convincing evidence that those skilled in the art would have found it non-enabling at the time the application was filed.

[34] The district court invalidated both patents for indefiniteness because of its view that some "trial and error" would be needed to determine the "lower limits" of stretch rate above 10% per second at various temperatures above 35°C. That was error. Assuming some experimentation were needed, a patent is not invalid because of a need for experimentation. *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270-71 (1916). A patent is invalid only when those skilled in the art are required to

engage in *undue* experimentation to practice the invention. *In re Angstadt*, 537 F.2d 498, 503-04, 190 USPQ 214, 218 (CCPA 1976). There was no evidence and the court made no finding that undue experimentation was required.

[35] Moreover, the finding here rested on confusion of the role of the specification with that of the claims. The court found that the specification's failure to state the lower limit of stretch rate (albeit above 10% per second) at each degree of temperature above 35°C (a requirement for at least hundreds of entries in the specification) did not "distinguish processes performed above the 'lower limit' from those performed below the 'lower limit'." The claims of the '390 patent say nothing of processes and lower limits. Distinguishing what infringes from what doesn't is the role of the claims, not of the specification. It is clear that the specification is enabling. *In re Storrs*, *supra*, and that the claims of both patents are precise within the requirements of the law. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

[36] The finding that "matrix tensile strength" is indefinite, like the other findings under §112, appears to rest on a confusion concerning the roles of the claims and the specification. While finding "matrix tensile strength" in the claims indefinite, the district court at the same time recognized that the specification itself disclosed how to compute matrix tensile strength, in stating "to compute matrix tensile strength of a porous specimen, one divides the maximum force required to break the sample by the cross sectional area of the porous sample, and then multiplies this quantity by the ratio of the specific gravity of the solid polymer divided by the specific gravity of the porous specimen." Further, the specification provided the actual matrix tensile strength in several examples. It is well settled that a patent applicant may be his own lexicographer. In light of the disclosure of its calculation in the specification, we cannot agree that "matrix tensile strength" is either indefinite or non-enabling.

Nor does absence from the specification of a definition for "specific gravity of the solid polymer," a part of the computation of matrix tensile strength, render that computation indefinite. It is undisputed that in the many examples in the application the specific gravity values used for unsintered and sintered PTFE were 2.3 and 2.2, respectively. There was no testimony that those values were not known to persons of ordinary skill in the art or could not be calculated or measured. There is simply no support for the conclusion that "specific gravity of the solid polymer" is indefinite or that absence of its definition ren-

ders the specification non-enabling. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

We conclude that Garlock has failed to prove that at the time the application was filed, the specification was not enabling or that the claims were indefinite within the meaning of §112.

(2) Fraud

[37] Fraud must be shown by clear and convincing evidence. *Norton v. Curtiss*, 433 F.2d 779, 797, 167 USPQ 532, 546-47 (CCPA 1970).

The state of mind of the one making the representations is probably the most important of the elements to be considered in determining the existence of "fraud." *** Good faith and subjective intent, while they are to be considered, should not necessarily be made controlling. Under ordinary circumstances, the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent. Where public policy demands a complete and accurate disclosure, it may suffice to show nothing more than that the misrepresentations were made in an atmosphere of gross negligence as to their truth. [emphasis in original].

Norton, 433 F.2d at 795-96; 167 USPQ at 545; see, *Miller*, *Fraud on the PTO*, 58 JPOS 271 (1976).

Garlock alleges fraud in Gore's representations that stretching PTFE tape at a rate greater than 10% per second was novel and that it produces a physical phenomenon. The district court found the evidence insufficient to establish that Gore had a specific intent to defraud the PTO. No basis exists for our overturning that finding. Accordingly, we agree with the district court that Garlock has failed to sustain its heavy burden of proving, by clear and convincing evidence, sufficient facts from which fraudulent intent can be inferred.

Garlock points to a September 4, 1975, Gore affidavit filed in the PTO that stated:

2. Prior to my invention disclosed in the captioned patent application, during production of expanded PTFE products by W. L. Gore & Associates, Inc., the rate of stretching was neither measured nor controlled, and to my knowledge did not involve stretching of unsintered PTFE at a rate exceeding about 10% per second. (emphasis in original)

No finding of the district court and no evidence of record establishes that that state-

ment was made in reckless disregard of facts from which an intent to defraud may be inferred.

The district court's finding in 1982 that the 401 machine inherently stretched tape at some time in 1969 at a rate more than 10% per second, does not establish that Dr. Gore was aware of that fact in 1975, nor does it make untrue his statement that to his knowledge that had not been the rate of stretch employed. Nor does the district court's finding conflict with Dr. Gore's statement that the rate of stretching was neither measured nor controlled in the Gore shop before his invention of the claimed process as a whole.

Nor does the evidence of isolated statements support Garlock's contention that Dr. Gore attempted to convince the PTO that a physical phenomenon always existed in which stretching at a rate greater than 10% per second always produced a matrix tensile strength greater than 7300 psi. On the contrary, Dr. Gore set forth in his specification examples indicating that some samples broke, ruptured, or disintegrated.

(3) Attorney's Fees

The district court did not abuse its discretion in denying Garlock its request for attorney fees.

Infringement

[38] Where, as here, an appellate court reverses a holding of invalidity, and remand is ordered for trial of the factual issue of infringement, an inefficient use of judicial resources results if the second judgment is appealed. The better practice would therefore be for the district court to decide both the validity and infringement issues when both are contested at the trial, enabling the conduct of a single appeal and disposition of the entire case in a single appellate opinion.

Resolution of the infringement issue at trial may also overlap with resolution of the validity issue, where, for example, the claimed invention was or was not copied by the validity challenger, or the challenger substituted the claimed invention for freely available prior art processes or products. *Eibel*, supra, 261 U.S. at 56, or an assertion of nonenablement may conflict with the ease with which the accused infringer may be shown to have practiced the invention as taught in the patent. *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 61 (1923).

[39] The district court having declined to decide the infringement issue, Gore suggests that the record here is sufficient to warrant

our deciding it now. With reluctance in view of the length and bitter nature of the present litigation, we decline the suggestion. In so doing, we imply nothing of our view on the issue. Nor do we intend any implication that the district court could not itself determine the infringement issue on the present record. Infringement of particular claims of two patents was asserted. None of those claims has been finally held invalid. Assuming their continued assertion, infringement must be decided with respect to each asserted claim as a separate entity. *Altoona, supra*, 294 U.S. at 487. Those factual determinations should be made in the first instance by the district court.

Decision

The holdings of invalidity of claim 1 of the '566 patent under §102(a) and of claim 17 of the '566 patent under §103, the determination that Gore did not commit fraud on the PTO, and the denial of attorney fees, are affirmed; the holdings that all claims of the '566 patent are invalid under §102(b); that claims 3 and 19 of the '566 patent are invalid under §103; and that all claims of the '566 patent are invalid under §112, are reversed. The holdings that claims 1, 9, 12, 14, 18, 35, 36, 43, 67, and 77 of the '390 patent are invalid under §§102 and 103, and that all claims of the '390 patent are invalid under §112, are reversed. The case is remanded for determination of the infringement issue.

Affirmed in part, reversed in part, and remanded.

Appendix

Claims of the '566 patent discussed at trial:

1. A process for the production of a porous article of manufacture of a polymer of tetrafluoroethylene which process comprises expanding a shaped article consisting essentially of highly crystalline poly (tetrafluoroethylene), made by a paste-forming extrusion technique, after removal of lubricant, by stretching said unsintered shaped article at a rate exceeding about 10% per second and maintaining said shaped article at a temperature between about 35°C. and the crystalline melt point of said tetrafluoroethylene polymer during said stretching.

3. The process of claim 1 in which the rate of stretch is about 100% per second.

17. The process of claim 1 in which the shaped article is expanded such that its final length in the direction of expansion is greater than about twice the original length.

19. The process of claim 17 in which said final length is greater than about five times the original length.

Claims of the '390 patent discussed at trial:

1. A porous material consisting essentially of highly crystalline polytetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils and has a matrix tensile strength in at least one direction above about 73,000 psi.

9. A porous material consisting essentially of polytetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils and has a matrix tensile strength in at least one direction above 9290 psi, which material has been heated to a temperature above the crystalline melt point of said polymer and has a crystallinity below about 95%.

12. A porous material in accordance with claim 9 which is in the form of a shaped article.

14. A product in accordance with claim 12 which is in the form of a film.

18. A product in accordance with claim 12 which is in the form of continuous filaments.

35. A laminated structure comprising (a) a first shaped article formed of a porous material made of a tetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils and has a matrix tensile strength in at least one direction above about 7,300 psi, and (b) a second shaped article bonded to said first shaped article.

36. The structure of claim 35 in which said first shaped article is formed of a porous material which has a matrix tensile strength in at least one direction of at least 9290 psi, and has a crystallinity below about 95%.

43. A porous material made of a tetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils, which material (a) has a matrix tensile strength in at least one direction above about 9290 psi, (b) has been heated to a temperature above 327°C. and has a crystallinity below about 95%, and (c) has a dielectric constant of 1.2-1.8.

67. An impregnated structure comprising

(a) a shaped article formed of a porous material made of a tetrafluoroethylene polymer which material has a microstructure characterized by nodes interconnected by fibrils and a matrix tensile strength in at least one direction above about 9290 psi; and

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(b) a polymer impregnated within the pores of the said shaped article.

77. The structure of claim 35 in which the first shaped article is a sheet having pores that will pass a gas but will not pass liquid water.

Davis, Circuit Judge, concurring in the result in part and dissenting in part.

I concur in the result on (1) the validity of the '390 patent under §§ 102-103; (2) the validity of the '390 patent under § 112; (3) the invalidity of claims 1 and 17 of the '566 patent; (4) lack of fraud on the Patent and Trademark Office; and (5) denial of attorneys' fees. I disagree and dissent as to the validity of claims 3 and 19 of the '566 patent.

1. The process invention embodied in claim 1 of the '566 patent was known, through use of the 401 machine in the Gore shop, well before the "invention date," (claimed by Robert Gore, the inventor) of October 1969.¹ As such, the claimed invention was invalid on at least three grounds: (i) it was anticipated and therefore would have been obvious (under 35 U.S.C. § 103) at the time of the claimed invention date; (ii) the invention was "in public use" by the Gore shop (under 35 U.S.C. § 102(b)) more than one year prior to the patent application (i.e., prior to May 21, 1969); and (iii) the invention (made by Robert Gore) was known to and used "by others in this country" (35 U.S.C. § 102(a)) before the claimed invention date of October 1969, i.e. the invention was used by Wilbert Gore and others in the Gore shop before the October date.²

The critically important aspect of the invention of the '566 patent is the stretching of PTFE at a rate above 10% per second.³ Robert Gore testified that he conceived this invention no earlier than October 1969 (and we have the right to take him at his word),⁴ but the facts found by the District Court plainly show that the Gore shop was in fact practicing that invention considerably earlier.

¹ The 401 machine was used under the prior '915 patent (issued to Wilbert Gore) which contains no reference to the significance of the rate of stretch.

² Aside from the bases I discuss, I do not reach the other grounds asserted for invalidity of the '566 patent.

³ Before the PTO Robert Gore concededly referred to this as "critical" to his invention or as his "invention."

⁴ The District Court found that October 1969 was the earliest date Robert Gore asserts for his conception of the invention in the '566 patent.

The District Court found that in the 401 machine the distance between the stretch rollers controls the rate of stretch; a shorter distance results in a higher rate of stretch; for the process described in the '915 patent to be practiced with a rate of stretch below 10% per second, the distance between the stretch rollers would have to be greater than five feet; if the distance is less than four feet, the rate of stretch is greater than 10% per second; the machine drawings used to construct the 401 machine indicate that the distance between the stretch rollers was eight inches; a Gore employee testified that "I am reasonably sure that no effective [stretch] rolls in question would have been more than three feet simply because of the nature and size of the equipment" and that he did not remember any stretching more than three feet; another Gore employee testified that the distance between the rollers was "a maximum of 18 inches" (emphasis added); a document prepared by the same employee (an engineer) on June 10, 1969 reports that the stretch span was 8 inches; the 401 machine was the only stretching machine used by the Gore company; and the 401 machine was never substantially changed before October 1969. All this adds up to the fact that the 401 machine was at all relevant times operated with a stretch of less than four feet.⁵ There is no question that the machine was so operated before October 1969 (the District Court found that sales of tape made by the 401 machine were proposed in August 1969).

I can accept Robert Gore's affidavit (to the PTO) that there was no stretching in the Gore shop at a rate exceeding about 10% per second prior to my invention disclosed in the captioned patent application" (emphasis added) only because that declaration was expressly qualified by the phrase "to my knowledge" (emphasis added). The District Court specifically found no specific intent by Robert Gore to defraud and, on this record, we

⁵ The Gores (Robert and Wilbert) testified at trial that the distance was five feet but there is no indication that the trial court (which did not cite this testimony but did cite the opposing evidence) credited the Gores' testimony.

⁶ The factor of the rate of stretching was of direct interest to the examiner during the prosecution of the '566 patent. In response to the examiner's express request for a declaration that the Gore firm's production of stretched PTFE tape, prior to Robert Gore's invention asserted here, did not involve stretching of unsintered PTFE at a rate exceeding about 10% per second, Robert Gore filed an affidavit in the PTO specifically stating that "to my knowledge" (emphasis added) the 401 machine did not involve stretching at a rate exceeding about 10% per second.

cannot properly overturn that finding. But the absence of personal intent to defraud does not mean or say that, whether Robert Gore realized it or not, the 401 machine was not actually operating, well before October 1969, to stretch unsintered PTFE at a rate exceeding about 10% per second. Cf. *O'Brien v. Westinghouse Electric Corp.*, 293 F.2d 1, 10 (3rd Cir. 1961). It seems impossible to me to reconcile Robert Gore's insistence on two facts—that (i) he invented the process in October 1969 and (ii) he had no knowledge prior to October 1969 of stretching PTFE at the critical rate—with the solid facts in the record as to the prior operation of the 401 machine, except on the view that Robert Gore did not realize that he and others in the Gore shop had made his invention previously.

2. It follows that in October 1969 the invention of '566 would have been obvious under §103 to Robert Gore because the prior practice of the 401 machine constituted prior art. Even if this was not prior art technically within §102, that statutory provision "is not the only source of prior art." *In re Fout*, 675 F.2d 297, 300 (CCPA 1982, emphasis in original). The 401 machine was practiced under the '915 patent (issued to Wilbert Gore) and, whether or not Robert Gore subjectively realized what was happening, he and others in the Gore shop were practicing the invention later embodied in the '566 patent. That was prior art at least as to Robert Gore. *Id.* at 300-01.⁷

3. If it be thought necessary to invoke §102 directly, in order to show anticipation, the record contains proof that the 401 machine was designed, constructed and used (just as described supra) in November and December 1968 and the early months of 1969—more than one year prior to the '566 patent application of May 21, 1970. See *Jt. App. E 1199*. E-1200. Section 102(b) therefore applies. Although commercial production was apparently not actively sought until June 1969, the practicing of the 401 machine prior to May 21, 1969 was "a public use" because the Gore company made "use of the device *** in the factory in the regular course of business." *Connecticut Valley Enterprises, Inc. v. United States*, 348 F.2d 949, 952, 146 USPQ 404, 406 (Ct. Cl. 1965).

⁷ The District Court has found that there are no differences between claim 1 of the '566 patent and the processes previously used by the Gore firm to produce paste-extruded unsintered PTFE.

4. Also, §102(a)⁸ applies here because Robert Gore was the inventor in the '566 patent and Wilbert Gore and others in the Gore shop were using the 401 machine before October 1969. Wilbert Gore (the inventor in the '915 patent under which the 401 machine was made and used) and the other employees are "others" within §102(a)—they are not the same as Robert Gore who claimed to be inventor of the process that ripened into the '566 patent.⁹ See also §102(f), which would bar Robert Gore if he did not himself invent the subject matter of the '566 patent.¹⁰

5. The majority sustains the validity of claims 3 and 19 of the '566 patent (the claims also involved in appellant's suit for infringement) which are dependent on invalid claim 1. Because of the invalidity of claim 1 the only possible novelty in claim 3 would be the requirement that the rate of stretch would be about 100% per second, and the possible novelty of claim 19 would be that the final length would be greater than about five times the original length. My position is that both of these added elements, if novel, would have been obvious to persons of ordinary skill in the art.

The defect in the majority's analysis is that it neglects the cardinal fact that the prior art included the 401 machine (discussed supra), not merely the earlier patents assessed in the majority opinion. The 401 machine directly involved PTFE itself, not conventional thermoplastic polymers. That machine also directly involved rapid stretching of PTFE at a rate markedly exceeding 10%. With this prior art of the 401 machine before him, an ordinary person skilled in the art would maximize stretch rate, if only to improve the machine's production rate. Cf. *In re Dwyer, Jewell, Johnson, McGrath, & Rubin*, 317 F.2d 203, 207, 137 USPQ 540 (CCPA 1963). Moreover, the very existence and operation of the 401 machine, which stretched PTFE rapidly without breaking, suggests to the skilled person the probability of stretching at even higher rates. Certainly, in the light of the 401 machine, skilled workers would see in at least

⁸ An invention is anticipated if it "was known or used by others in this country *** before the invention thereof by the applicant for patent" (emphasis added).

⁹ It is undisputed that it was Wilbert Gore who initiated the project for the 401 machine and watched over it.

¹⁰ The majority's discussion of "secondary considerations," though it is relevant to other aspects of this case, is irrelevant to the issue of anticipation raised by the 401 machine, and hardly persuasive as to the issues of obviousness based on or with respect to the 401 machine.

the prior Markwood, Nash, and Scarlett patents (teaching extensive and rapid stretching of non-PTFE thermoplastics) the suggestion that the method of the 401 machine could also be used for comparable rapid and extensive stretching of PTFE.

6. In sum, I cannot escape the conclusion that--although there was no fraud proved--if the true facts as to the 401 machine had been made known to the PTO (as it requested), the involved claims of the '566 patent should (and probably would) not have been accepted.

Court of Appeals, Second Circuit

Harper & Row, Publishers, Inc. et al.
v. Nation Enterprises et al.

Nos. 83-7277 and 83-7327

Decided Nov. 17, 1983

COPYRIGHTS

1. In general (§24.01)

Copyright Act sets out test for preemption of state statutory or common law that may conflict with federal policies embodied in Act.

2. Matter copyrightable — Classes in statute (§24.303)

Work of authorship in which rights are claimed must fall within "subject-matter of copyright" as defined in Copyright Act Sections 102 and 103; Act embraces "works of authorship," including "literary works," as within its subject matter.

3. Matter copyrightable — In general (§24.301)

Fact that portions of memoirs may consist of uncopyrightable material does not take work as whole outside subject matter protected by Copyright Act; were this not so, states would be free to expand perimeters of copyright protection to their own liking, on theory that preemption would be no bar to state protection of material not meeting federal statutory standards; that interpretation would run directly afoul of one of Act's central purposes, to avoid development of any vague borderline areas between state and federal protection.

4. In general (§24.01)

Copyright Act requires that state law create legal or equitable rights that are equiv-

alent to any of exclusive rights within general scope of copyright as specified in Section 106 if it is to be preempted; these include rights to reproduce copyrighted work in copies, and to prepare derivative works based upon copyrighted work; when right defined by state law may be abridged by act that, in and of itself, would infringe one of exclusive rights, state law in question must be deemed preempted; conversely, when state law violation is predicated upon act incorporating elements beyond mere reproduction or the like, rights involved are not equivalent, and preemption will not occur.

5. Rights embraced in copyright (§24.50)

There is no qualitative difference between right of author and his licensed publishers to exercise and enjoy benefit of pre-book publication serialization rights, and exclusive right under Copyright Act of preparing derivative works based on copyrighted work; enjoyment of benefits from derivative use is so intimately bound up with right itself it could not possibly be deemed separate element.

6. In general (§24.01)

Fact that plaintiffs pleaded additional elements of awareness and intentional interference, not part of copyright infringement claim, in support of state law claim, goes merely to scope of right; it does not establish qualitatively different conduct on part of infringing party, nor fundamental non-equivalence between state and federal rights implicated.

7. Matter copyrightable — In general (§24.301)

Copyright Act protects only original works of authors; it grants rights not in ideas or facts, but in expression; one reasonable interpretation of word "discovery" in statute is "fact"; for example, historian who learns in his research that certain event has occurred has discovered fact; copyright does not preclude others from using ideas or information revealed by author's work; Act is thus able to protect authors without impeding public's access to information that gives meaning to our society's highly valued freedom of expression; neither news events, historical facts, nor facts of biographical nature are deserving of Act's protection; listing of names, nouns, or information is indisputably copyrightable as compilation, but preexisting facts contained in those lists are not protected.

8. Matter copyrightable — In general (§24.301)

Distinction between fact and expression is not always easy to draw; author's originality

fore, we affirm the district court's denial of AHP's motion to amend the permanent injunction.

CONCLUSION

In appeal no. 91-1147 we hold the district court correctly refused to hold claims 5, 19, 40, and 43 of the '322 patent invalid. In appeal no. 91-1157 we hold the district court did not abuse its discretion in denying costs and attorney fees to cross-appellants and in refusing to alter the terms of the permanent injunction.

AFFIRMED

Appendix



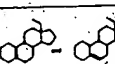




911 patent (A23-150)		gon-3(10)-diene
909 patent (A214-238)		gon-3(10)-diene
901 patent (A209-217)		gon-3(10)-ene and 5(10)-ene (mixture)
717 patent (A308-322)		8-iso-gonane
169 patent (A223-239)		gon-3(10)-ene
714 patent (A249-267)		gon-1,2,3(10)-triene
699 patent (A333-346)		9-hydroxy-gon-4-ene-3,17-dione (specie)

Figure 1.

U.S. Patent and Trademark Office Board of Patent Appeals and Interferences

Buell v. Beckstrom

No. 102,223

Decided January 10, 1992

Released January 22, 1992

PATENTS

1. Patentability/Validity — Date of invention — Reduction to practice (§115.0405)

Patentability/Validity — Date of invention — Suppression or concealment (§115.0407)

Issue of abandonment, suppression, or concealment, within meaning of 35 USC 102(g), cannot arise unless and until prior actual reduction to practice has been established; thus, in interference proceeding in which parties' preliminary statements have not been opened for inspection and in which examiner in chief has declined to schedule testimony period, party's actual reduction to practice has not been established, and opposing party cannot properly raise issue of abandonment, suppression, or concealment at this time.

2. Practice and procedure in Patent and Trademark Office — Reissue — Time for application (§110.1307)

Practice and procedure in Patent and Trademark Office — Reissue — Broader claims sought (§110.1313)

Examiner in chief did not err in concluding that party is not precluded by two-year limitation of 35 USC 251 from presenting claims in his involved reissue application that are broader than those claims issued in original patent, in view of evidence showing that party filed broadening reissue application that sought to enlarge scope of re-examined claims of patent and that was considered to be filed within two-year period, and, while that application was still pending, filed involved reissue application as division of pending application.

Trademark Office Appeals and Interferences

Beckstrom

102,223

January 10, 1992

January 22, 1992

Validity — Date of inven-
tion to practice

Validity — Date of inven-
tion or concealment

invention, suppression, or
concealment of 35 USC
102(b) unless and until prior
art has been estab-
lished by an interference proceeding in
which primary statements have
been made and in which
as declined to schedule
the actual reduction to
practice has been estab-
lished, and opposi-
tion has been raised or
concealment at this

Procedure in Patent and
Appeal — Reissue — Time
§110.1307)

Procedure in Patent and
Appeal — Reissue —
Sought (§110.1313)

did not err in concluding
that the claims were precluded by two-year
under 35 USC 102(b) from presenting
a reissue application that
the claims issued in origi-
nal evidence showing that
the reissue application
was outside the scope of re-examination
that was considered to
be pending, and, while
still pending, filed in
division of pend-

Particular patents — General and me- chanical — Disposable brief

4,704,115, Buell, disposable waste con-
tainment garment, junior party in interfe-
rence held not entitled to patent with claims 1
through 6, 8, 12, 16, and 19 corresponding to
the count.

Interference proceeding involving patent
granted to Kenneth B. Buell on Nov. 3,
1987, patent no. 4,704,115, filed April 10,
1986, serial no. 06/851,864, accorded bene-
fit of serial no. 06/697,531, filed Feb. 1,
1985, and application of Bo Beckstrom,
filed Nov. 2, 1988, serial no. 07/267,224,
accorded benefit of serial no. 06/440,947,
filed Nov. 12, 1982, now patent no.
4,490,148, issued Dec. 24, 1984 (disposable
waste containment garment). Judgment en-
tered against both parties.

John C. Vassil, Jerome G. Lee, and John F.
Sweeney, New York, N.Y.; Thomas J.
Slone, Richard C. Witte, Thomas H.
O'Flaherty, Frederick H. Braun, and Ste-
ven W. Miller, Cincinnati, Ohio; Stanley
Schwartz, Arlington, Va., for Buell.

John P. Milnamow and Allen J. Hoover,
Chicago, Ill.; Robert J. Patch, Arlington,
Va., for Beckstrom.

Before Calvert, vice chairman, and
Urynowicz and Staab, examiners-in-chief.

Staab, examiner-in-chief.

This interference involves a patent to
Buell, U.S. Patent No. 4,704,115, issued
November 3, 1987 and assigned to The
Procter & Gamble Co., and a reissue appli-
cation of Beckstrom, Serial No. 267,224,
filed November 2, 1988 and assigned to
Landstingens Inkopscentral of Solna,
Sweden.

The subject matter of the interference
relates to a waste containment garment such
as a disposable brief for incontinent adults or
a diaper. Count 1 is the sole count in issue,
and it reads as follows:

Count 1

A waste containment garment having a
rear waistband region, a front waistband
region, and a crotch region, said garment
comprising:

- a liquid permeable topsheet;
- a liquid impervious backsheet;
- an absorbent core intermediate said top-
sheet and said backsheet;
- two inwardly facing, longitudinally ex-
tending, impermeable side-edge-leakage
guard gutters having proximal and distal
edges, said gutters being disposed adja-

cent the longitudinal side edges of the
garment;

means for longitudinally elasticizing
said gutters adjacent said distal edges, the
garment being sized and configured with
respect to the user to enable said distal
edges to contact torso areas of the user
throughout the lengths of said distal edges
and to substantially preclude said distal
edges from encircling the thighs of the
user;

means for securing the garment on the
user so that laterally directed tension is
applied to portions of said proximal edges
of said gutters which extend between the
ends of the garment and the upper thigh
elevation of the user; and

means for substantially obviating inver-
sion of said gutters during application and
use of the garment.

The claims of the parties which corre-
spond to the count are:

Buell: claims 1-6, 8, 12, 16 and 19.

Beckstrom: claims 26-29.

The following preliminary motions were
filed:

(1) Buell's motion under 37 CFR 1.633(a)
for judgment as to Beckstrom's claims 26
through 29 on the ground that they are
unpatentable under 35 USC 112, first para-
graph, as being based upon a specification
that does not provide descriptive support for
all the limitations of the claims (Paper No.
9).

(2) Buell's motion under 37 CFR 1.633(a)
for judgment as to Beckstrom's claims 26
through 29 on the ground that they are
unpatentable under 35 USC 251 on the ra-
tionales that: (a) claims 26 through 29 are
broadening reissue claims filed more than
two years after the original patent issued
and/or (b) Beckstrom has not established
that claims 26 through 29 were not included
in the original patent because of "error"
(Paper No. 10).

(3) Beckstrom's motion under 37 CFR
1.633(f) to be accorded the benefit of the
filing date of Swedish Patent Application
Serial No. 8204083-3 filed July 1, 1982
(Paper No. 12).

(4) Beckstrom's motion under 37 CFR
1.633(c)(2) to amend claim 26 (Paper No.
13).

(5) Beckstrom's motion under 37 CFR
1.633(f) to be accorded the benefit of the
Swedish Patent Application referred to in
(3) with respect to claim 26 as amended in
(4) (Paper No. 14).

(6) Beckstrom's motion under 37 CFR
1.633(c)(3) to redefine the interference by
also designating claims 3 through 6, 8 and 16

of Buell's patent as corresponding to the count (Paper No. 15).

(7) Beckstrom's motion under 37 CFR 1.633(a) for judgment as to Buell's claims corresponding to the count on the ground that they are unpatentable under 35 USC 102 and 103 over prior art, which prior art is not applicable to Beckstrom (Paper No. 17).

(8) Beckstrom's motion under 37 CFR 1.635 for judgment as to Buell's claims corresponding to the count on the ground that they are unpatentable under 35 USC 112, second paragraph (Paper No. 28).

Oppositions were filed in response to all of the above motions except motions (4) and (6).

In a decision mailed June 14, 1990 (Paper No. 31), the Examiner-in-Chief (EIC) granted Buell's motion (1) because Beckstrom's involved application does not have support for the limitation "means for securing the garment on the user so that laterally directed tension is applied to portions of said proximal edges of said gutters which extend between the ends of the garment and the upper thigh elevation of the user" as set forth in claim 26. The EIC also granted Buell's motion (2), reasoning that since Beckstrom does not have support for the above quoted portion of claim 26, it could not have been error not to claim that subject matter. As to Buell's alternative rationale offered in support of motion (2), the EIC concluded that Beckstrom's involved reissue application is entitled to contain claims broader than the claims of the original patent since the involved reissue application is entitled under 35 USC 120 to the benefit of the filing date of an intervening reissue application filed within two years of the original patent. The EIC also denied Beckstrom's motions (3) and (5) because Beckstrom's involved application does not support all the limitations of claim 26. The EIC denied Beckstrom's motion (7) because he concluded that the moving party failed to show that the subject matter of Buell's claims corresponding to the count was anticipated by or would have been obvious in view of the cited references. Finally, the EIC denied Beckstrom's motion (8) that Buell's claims corresponding to the count are unpatentable for failing to particularly point out and distinctly claim the invention which Buell regards as his invention. Pursuant to 37 CFR 1.640(d)(1), Beckstrom was ordered to show cause why judgment should not be entered against him in accordance with the EIC's decisions.

Beckstrom filed a response to the order to show cause wherein Beckstrom attempted to show good cause why judgment should not

be entered in accordance with the EIC's decisions. Beckstrom also filed a request for a testimony period, which was denied, and a request for a final hearing. In addition, Beckstrom filed notice under 37 CFR 1.632 of his intention to argue at final hearing that Buell abandoned, suppressed or concealed an actual reduction to practice. Both parties filed briefs and appeared, through counsel, at final hearing for oral argument.

[1] At the outset, we observe that the issue of abandonment, suppression or concealment, within the meaning of 35 USC 102(g) "cannot arise unless and until a prior actual reduction to practice has been established." *Connin v. Andrews*, 223 USPQ 243, 249 (Bd. Pat. Int'l. 1984). Also, see *Peeler v. Miller*, 535 F.2d 647, 190 USPQ 117 (CCPA 1976). Since the parties' preliminary statements have not been opened for inspection and since the EIC has declined to schedule a testimony period, Buell's actual reduction to practice has not been established. Therefore, Beckstrom cannot properly raise the issue of abandonment, suppression or concealment at this time.

The issues to be decided are:

I. Whether Beckstrom has 35 USC 112, first paragraph, support for his claims corresponding to the count.

II. Whether Beckstrom's involved reissue application filed outside the two year limitation of 35 USC 251 should be accorded, pursuant to 35 USC 120, the benefit of the filing date of an intervening broadening reissue application filed within the two year limitation of §251 for the purpose of enlarging the scope of the claims of the original patent.

III. Whether Buell's claims corresponding to the count are patentable to Buell under 35 USC 102 and/or 35 USC 103.

IV. Whether Buell's claims corresponding to the count particularly point out and distinctly claim the subject matter sought to be patented as required by the second paragraph of 35 USC 112.

I. Beckstrom's Support for His Claims Corresponding to the Count.

The EIC correctly decided that the disclosure of the involved Beckstrom application does not provide adequate descriptive support for the limitation "means for securing the garment on the user so that laterally directed tension is applied to portions of said proximal edges of said gutters which extend between the ends of the garment and the upper thigh elevation of the user" which appears in claim 26.

Beckstrom contends that support for this limitation is found in column 1, lines 54

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through 57, of his original patent (U.S. Patent No. 4,490,148) which reads: "(u)sually the diaper according to the invention is held in place with a pair of briefs, which are known per se, but it is also possible to use a girdle, band, tape or the like to hold the diaper in place." It is argued that one skilled in the art would expect tape to function so as to apply lateral tension to the proximal edges of the gutters and/or that the use of tape to hold the diaper in place would inherently provide the recited function of applying laterally directed tension. We cannot accept this argument.

As noted by the EIC in his decision on motions, the prior art patents to Strickland et al (U.S. Patent No. 4,253,461) and Buell (U.S. Patent No. 3,848,594) mentioned on page 17 of Beckestrom's brief are not cited in the original Beckestrom patent and therefore cannot be relied upon for a description that is lacking in the disclosure of the involved Beckestrom application. Furthermore, we are not convinced by Beckestrom's pronouncements regarding what is "conventionally understood" in the art (brief, page 17) that one skilled in the art would know from reading Beckestrom's disclosure that the tape referred to therein is to function so that lateral tension is applied to the proximal edges of the gutters to hold the diaper in place. Regarding the argument that the use of tape inherently results in the claimed function, we see no reason to conclude that this is necessarily so, especially since Beckestrom's disclosure offers no hint of such a function and since Beckestrom's specification groups tape with other holding means, such as briefs, a girdle and a band, which are seen as providing compression to the edges of the gutters rather than lateral tension. Accordingly, we are not persuaded that the EIC was in error in determining that Beckestrom's application does not have 35 USC 112 support for the subject matter of claims 26 through 29.

II. Beckestrom's Right to Present Claims Broader than Those Claims Issued in His Original Patent.

Beckestrom's application S.N. 440,947 filed November 12, 1982 for an invention entitled PROTECTOR AGAINST INCONTINENCE OR DIAPER issued as U.S. Patent No. 4,490,148 on December 25, 1984. The '148 patent was subjected to a reexamination procedure which resulted in the issuance of a reexamination certificate narrowing the scope of the claims of the original patent. On December 29, 1986, two years and four days after issuance of the original patent, Beckestrom filed broadening

reissue application S.N. 948,531 seeking to enlarge the scope of the reexamined claims of the '148 patent. Because December 25, 26, 27 and 28, 1986 were non-business days in the Patent and Trademark Office, the '531 application was considered to be filed within the two year period under 35 USC 251 for a reissue application enlarging the scope of the claims of the original patent. On November 2, 1988, while the '531 application was still pending, and nearly four years after the '148 patent issued, Beckestrom filed the involved reissue application S.N. 267,224 as a division² of the '531 application, together with a preliminary amendment adding claims 26 through 29. Claims 26 through 29 of the '224 application, which correspond to the count of the present interference, are acknowledged to be broader than both the original and reexamined claims of the '148 patent.

Beckestrom argues that since the PTO recognized his earlier '531 reissue application as being filed within the two year period prescribed by 35 USC 251, his divisional reissue application should have the same effect as though such application had been filed on the date when the earlier broadening reissue application was filed. Beckestrom cites *In re Bauman*, 683 F.2d 405, 214 USPQ 585 (CCPA 1982) for the proposition that reissue applications continuing from reissue applications are within the scope of §120 and *In re Hogan*, 559 F.2d 595, 604, 194 USPQ 527, 536 (CCPA 1977) for the proposition that section 120 is applicable to all bases of rejection. Beckestrom also cites *In re Doll*, 419 F.2d 925, 164 USPQ 218 (CCPA 1970) for the proposition that broadening claims may be presented in a reissue application filed within two years after a patent grant even though such claims were not presented until more than two years after

On November 7, 1989, the '531 application issued as patent No. Re. 33,106. Apparently, neither the '531 application nor the involved '224 application was referred to the Commissioner pursuant to 37 CFR 1.177. According to said regulation, the '531 application should have been withheld from issue until the controversy surrounding the involved '224 reissue application was resolved in the absence of an order from the Commissioner. The involved reissue application will be forwarded to the Commissioner in due course.

The '224 reissue application would appear to be directed to the same invention as the '531 reissue application. However, in order to avoid confusion as to the application intended, we will continue to refer to the '224 reissue application as a division rather than a continuation of the '531 application.

the patent grant and were broader than the original patent claims and the broadened reissue claims originally submitted.

Buell contends that the EIC's decision according Beckstrom's '224 divisional reissue application the benefit of the '531 reissue application's filing date pursuant to 35 USC 120 is based on a misinterpretation of *Bauman* and *Hogan* that circumvents the express two year limitation on broadening reissue applications of 35 USC 251. In Buell's opinion, *Bauman* and *Hogan* are distinguishable because the two year limitation of section 251 was not implicated in either of these cases. As to *Doll*, Buell notes that the further broadening claims in that case were added by amendment in a timely filed application for a broadening reissue rather than in a separate application filed outside the two year limitation. Buell argues that an extension of time of the two year limitation of §251 is against public policy and cites *In re Fortland*, 779 F.2d 31, 228 USPQ 193 (Fed. Cir. 1985) in support of this argument. Buell cites *Stohr v. Brenner, Comr. Pats.*, 157 USPQ 675 (D.D.C. 1968), *aff'd*, 417 F.2d 1149, 162 USPQ 73 (D.C. Cir. 1969), for the proposition that continuing applications cannot be used as a vehicle for obtaining a potentially unrestricted extension of time in which to file a broadening reissue application. From Buell's perspective, *Stohr* is the only case in which the policies behind both §120 and the two year limitation of §251 were implicated.

[2] There is no dispute that the involved reissue application satisfies the basic statutory requirements of section 120 of copendency, continuity of inventorship, and reference to the earlier application. For purposes of this discussion, we shall assume that the invention sought to be patented was "disclosed in the manner provided by the first paragraph of section 112" as also required by section 120. In *Bauman*, the court, in holding that a regular, nonreissue application can be entitled to the benefit of the filing date of a reissue application under section 120, noted at 214 USPQ 587 that "[i]ndeed, the PTO acknowledges that reissue applications continuing from reissue applications are within the scope of section 120." Moreover, in *Hogan*, the court said at 194 USPQ 536 that "[n]othing in §120 limits its application to any specific grounds of rejection" and that "symmetry of the law, and evenness of its application, require that §120 be held applicable to all bases for rejection, that its words 'same effect' be given their full meaning and intent." The court was there referring to the language of section 120 which provides "an application . . . shall have the

same effect, as to such invention, as though filed on the date of the prior application." In light of *Doll*, *Bauman* and *Hogan*, we believe that the EIC was correct in concluding that Beckstrom is not precluded by the two year limitation of 35 USC 251 from presenting claims in his involved reissue application to the invention disclosed in his original patent that are broader than the claims of the patent.

As to the *Stohr* case cited by Buell for the proposition that continuing applications cannot be used to circumvent the two year limitation of section 120, the facts in *Stohr* are vague and other factors, possibly relevant, are present. No analysis pertinent to the issue presented here is provided. Accordingly, we do not consider *Stohr* to be of assistance in deciding the issue before us.

III. The Patentability of Buell's Claims Corresponding to the Count Under 35 USC 102 and/or 35 USC 103.

We agree with Beckstrom that the EIC erred in determining that Buell's claims corresponding to the count were patentable over the prior art cited by Beckstrom. Specifically, it is our view that Buell's claims corresponding to the count are unpatentable under 35 USC 103 over Beckstrom's Japanese Patent (Unexamined Publication) No. 59-25741 published February 9, 1984 or Beckstrom's European Patent No. 98,512 A2 published January 18, 1984, in view of U.S. Patent No. 4,253,461 to Strickland or U.S. Patent No. 4,500,316 to Damico.

The diapers of each of the Beckstrom patents include a liquid permeable topsheet 29, a liquid impervious backsheet 16, and an absorbent core 10 intermediate the topsheet and the backsheet. The folded end edge strips 17, 18 comprise leakage guard gutters and the elastic strips 21, 22 comprise means for longitudinally elasticizing the gutters adjacent the distal edges thereof. Since the strips of Beckstrom extend the entire length of the garment and have a width approximately one-fourth to one-third the width of the diaper (European specification, page 5; Japanese translation, pages 7-8), we consider Beckstrom's garment to be sized and configured to enable the distal edges of the strips to contact torso areas of the user throughout the lengths of the distal edges and not encircle the thighs of the user. In this regard, the statement in Beckstrom's European and Japanese patents to the effect that the free edges of the strips fit into folds of the thigh in the crotch area of the user neither suggests nor requires encirclement of the thigh by the free edges, as argued by Buell. The connection of the ends 25, 26, 27 and 28 of the edge

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from that the EIC Buell's claims core patentable over Beckstrom. Specificall- iell's claims corre- unpatentable un- Beckstrom's Japanese blication) No. 59- y 9, 1984 or Beck- it No. 98,512 A2 34, in view of U.S. Strickland or U.S. Damico.

f the Beckstrom ermeable topsheet cksheet 16, and an idiate the topsheet folded end edge cage guard gutters 2 comprise means ing the gutters ad- hereof. Since the d the entire length a width approxi- third the width of cification, page 5; s 7-8), we consider e sized and confi- edges of the strips e user throughout lges and not encir- In this regard, the s European and ffect that the free olds of the thigh in r neither suggests of the thigh by the Buell. The connec- and 28 of the edge

strips to the topsheet 29 prevents, at least to some degree, inversion of the strips during application and use and therefore constitutes means for substantially obviating inversion, as claimed. Beckstrom states that the diaper is secured to the user by panties or a hip belt, etc. (European specification, page 3) or a brief, girdle, band, tape or the like (Japanese translation, page 5). Accordingly, the Beckstrom patents disclose the invention of claim 26 except for means for securing so that laterally directed tension is applied to portions of the proximal edges of the gutters which extend between the ends of the garment and the upper thigh elevation of the user.

Strickland discloses securement means in the form of tapes 15, well-known in the art, which provide laterally directed tension to the waist area portion of the disposable incontinent brief. See column 6, lines 20 through 26. Similarly, Damico states that tapes 18a, b and c, similar to those in use on conventional disposable diapers, establish laterally directed lines of resistance which oppose lateral waist band contracting forces in the disclosed incontinent garment. See column 6, lines 3 through 20. It would have been obvious to one of ordinary skill in the art, seeking to improve upon the incontinent garment or diaper of Beckstrom, to provide tape type securement means in the waist area of Beckstrom's garment in order to take advantage of the known convenience such tapes provide. In applying such tape fasteners, the ordinarily skilled artisan would attach them to the outer edges of the garment in the waist area of the user, i.e., to the proximal edges of Beckstrom's strips or gutters 17, 18 at the upper thigh elevation of the user. As is evident from the above noted portions of Strickland and Damico, the provision of tapes in Beckstrom according to the teachings of the secondary references would establish laterally directed lines of resistant in the waist area of the garment.

In arriving at our conclusion, we have fully considered Buell's argument that there is no teaching in the applied references of applying laterally directed tension to the proximal edges of the gutters to keep the gutters open. However, this argument fails at the outset because it is predicated upon a limitation that is not present in Buell's claims corresponding to the count. See *In re Self*, 671 F.2d 1344, 213 USPQ 1 (CCPA 1982).

IV. The Patentability of Buell's Claims Corresponding to the Count Under 35 USC 112, Second Paragraph.

In opposing Beckstrom's motion (7) that Buell's claims corresponding to the count are

unpatentable under 35 USC 103, Buell argued that there is no teaching or suggestion in the prior art of applying lateral tension to keep the leakage-guard gutters open and fit to the wearer during use as required by the Buell invention. In response, Beckstrom filed motion (8) alleging that since Buell now considers his invention to include applying lateral tension to keep the gutter open and since the claims corresponding to the count do not require this feature, Buell's claims do not particularly point out and distinctly claim the invention which Buell regards as his invention, as required by the second paragraph of 35 USC 112. Buell maintains that when construed in light of the specification, one of ordinary skill in the art would understand the laterally directed tension applied to the proximal edges of the gutters causes the gutters to remain open during use.

It is axiomatic that during the prosecution of a patent application, claims are to be given their broadest reasonable interpretation. See *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). We agree with Beckstrom that Buell's claims do not require the laterally directed tension to be applied such that the gutters remain open during use. However, this fact by itself is not offensive to the second paragraph of 35 USC 112. While the claim language under consideration may be broad, breadth is not indefiniteness. See *In re Gardner*, 427 F.2d 786, 166 USPQ 138 (CCPA 1970). Instead, the second paragraph of section 112 simply requires the claims to set forth and circumscribe a particular area with a reasonable degree of precision and particularity. See *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). This Buell has done. Accordingly, we conclude that Buell's claims corresponding to the count are not unpatentable under 35 USC 112, second paragraph.

In view of our findings above that Beckstrom's claims corresponding to the count do not have proper descriptive support under 35 USC 112, first paragraph, and that Buell's claims corresponding to the count are not patentable to Buell under 35 USC 103, judgment against both parties is entered herein below.

Judgment

Judgment as to the subject matter of the count in issue is hereby awarded against Kenneth B. Buell, the junior party. The junior party Buell is not entitled to his patent with claims 1 through 6, 8, 12, 16 and 19 corresponding to the count.

Judgment as to the subject matter of the count in issue is hereby awarded against Bo

Beckstrom, the senior party. The senior party Beckstrom is not entitled to a patent with his claims 26 through 29 corresponding to the count.

suit and threats of suits to maintain monopoly status.

Particular patents — Electrical — Electrical filters

4,451,803, Holdsworth, Hesler, and DuBois, split tuning filter, partial summary judgment striking defendants' affirmative defenses issued.

District Court, N.D. New York

Eagle Comtronics Inc. v. Northeast Filter Co. Inc.

No. 90-CV-573

Decided November 22, 1991

PATENTS

1. Infringement — Defenses — Estoppel; laches (§120.1103)

Title — Assignments (§150.03)

Question of whether assignor was misled on inventorship and patentability relates to viability of patent application and not to validity of assignment agreement.

2. Title — Assignments (§150.03)

Employees' assignment of patent rights to employer for "one dollar and other good and valuable considerations" is not void and unenforceable for lack of consideration, since employees received salaries, bonuses, medical insurance, and other employment benefits both before and after assignment; even if portion of such benefits constituted past consideration, such conclusion would not render assignment void.

3. Infringement — Defenses — Estoppel; laches (§120.1103)

Doctrine of assignor estoppel applies not only to defendant who was formerly employed by plaintiff and who assigned patent rights to plaintiff but also to defendant corporation which was co-founded by former employee, since privity exists between individual defendant and corporate defendant.

4. Infringement — Defenses — Estoppel; laches (§120.1103)

Patent misuse — Federal antitrust issues (§140.07)

Patent infringement defendants who are estopped, under doctrine of assignor estoppel, from challenging plaintiff's infringement claims on grounds of patent invalidity cannot couch their arguments in terms of antitrust violations and claim that patent was acquired fraudulently and that plaintiff is attempting to enforce fraudulent patent by

Action by Eagle Comtronics Inc. against Northeast Filter Co. Inc. and Timothy M. Holdsworth for patent infringement, in which defendants counterclaim. On plaintiff's motion for partial summary judgment, and to strike defendants' counterclaims and affirmative defenses, and on defendants' counter motion for summary judgment. Plaintiff's motion granted.

Roger W. Parkhurst, of Parkhurst, Wendel & Rossi, Alexandria, Va., and Walter D. Kogut, of Scolaro, Shulman, Cohen, Lawler & Burstein, Syracuse, N.Y., for plaintiff.

Richard C. Conover, Bozeman, Mont., for defendants.

McCurn, C.J.

I.

INTRODUCTION

On January 23, 1991, plaintiff moved this court for partial summary judgment pursuant to Fed. R. Civ. P. 56 and to strike all of defendants' counterclaims and affirmative defenses premised on patent invalidity, laches, and equitable estoppel pursuant to Fed. R. Civ. P. 12(f). In response, defendants counter-moved for summary judgment pursuant to Fed. R. Civ. P. 56. The basis for this counter-motion is defendants' allegation that patent 4,451,803 ("803 patent") is invalid and that therefore, as a matter of law, there can be no infringement.

After considering the briefs of both parties and hearing oral argument on October 15, 1991, the court concludes that the doctrine of assignor estoppel applies to this action, and that therefore defendants are estopped from using patent invalidity as a defense to plaintiff's infringement claims. The court further concludes that the doctrines of laches and equitable estoppel are not available to defendants herein.

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Court of Customs and Patent Appeals

In re MILLER

No. 8444

Decided May 13, 1971

PATENTS

1. Claims — Indefinite — In general (§20.551)

First sentence of second paragraph of 35 U.S.C. 112 requires only that claims set out and circumscribe a particular area with a reasonable degree of precision and particularity; in absence of contrary evidence, court assumes that what the claims define is what applicant regards as his invention; if those skilled in the art can tell whether any particular powder is or is not within scope of claim, the claim fulfills its purpose as a definition; claim should not be denied solely because of type of language used to define subject matter for which patent protection is sought.

2. Claims — Indefinite — Chemical (§20.553)

Claims reciting that particles have, upon pressure molding, a specific flex strength are not defective under 35 U.S.C. 112 solely because such property can be measured only after powder has been compacted, since it is clear which particles fall within scope of claims and since mechanics of determining strength of particles are set forth in specification, and they do not appear to require unreasonable effort.

3. Claims — Indefinite — In general (§20.551)

Even if claims are broader than they otherwise would be if temperature had been specified, breadth is not to be equated with indefiniteness.

4. Pleading and practice in Patent Office — Rejections (§54.7)

Too much should not be required, in ex parte action, of applicant to rebut Patent Office's mere suspicions, based on no suggestion in prior art of record, that some other combination of process limitations might result in higher strength; court accepts applicant's evidence as establishing that his invention enables those skilled in the art to produce preforms of strength greater than strongest preforms obtainable with prior art method.

Particular patents — Polytetrafluoroethylene

Miller, Ultrafine Particles of Polytetrafluoroethylene and a Method for Making Them, claims 1, 2, and 4 to 18 of application allowed.

Appeal from Board of Appeals of the Patent Office.

Application for patent of William A. Miller, Serial No. 321,353, filed Nov. 4, 1963; Patent Office Group 140. From decision rejecting claims 1, 2, and 4 to 18, applicant appeals. Reversed.

JAY P. FRIEDENSON, Madison, N. J., for appellant.

S. WM. COCHRAN (JOSEPH F. NAKAMURA of counsel) for Commissioner of Patents.

Before RICH, ALMOND, BALDWIN, and LANE, Associate Judges, and FORD, Judge, United States Customs Court, sitting by designation.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 1, 2, and 4-18 in appellant's application serial No. 321,353, filed November 4, 1963, for ultrafine particles of polytetrafluoroethylene and a method for making them. We reverse.

The Invention

Polytetrafluoroethylene (hereinafter "PTFE") is the plastic well known under the trademark "Teflon." We are told that it is sold commercially in both powdered and powdered ultrafine form and that the powdered ultrafine PTFE as is and the powdered PTFE after further comminution are used to fabricate shaped articles. PTFE powder does not melt and flow even when heated under pressure, but ultrafine PTFE particles can be shaped under high pressure in a mold to a preform sufficiently strong and coherent to be removed from the mold. The preform can then be heated in a furnace to a temperature at which sintering occurs, resulting in coalescence of the particles into usable articles of the same shape as the preform.

Appellant claims PTFE in finely powdered, non-fibrous form and a method of preparing the powdered product consisting of grinding the PTFE powder commercially available in a particular type of air mill which is concededly old for other purposes. Commercially available PTFE powder has been ground in other types of air mills into ultrafine, fibrous particles before premolding, but appellant maintains that grinding such pow-

der in this particular type of air mill, which mills and classifies sequentially, rather than simultaneously as in the previously used air mills, results in *non-fibrous*, ultrafine PTFE powder with significantly improved preform strength (unsintered flex strength). This is said to be advantageous because it reduces scrap reworking due to cracking on removal from the mold. Claims 1 and 2 are reproduced as illustrative, with subparagraphings supplied and the recitations principally in controversy emphasized:

1. A method for preparing polytetrafluoroethylene adapted for molding precision parts and thin sheeting, comprising

the sequential steps of

(a) subjecting particles of polytetrafluoroethylene, which particles are at least 100 microns in their smallest dimension, to milling effected substantially solely by interparticulate collision, at a temperature of less than about 200°F;

(b) classifying the milled particles to separate therefrom particles having a maximum dimension of up to and including about 50 microns, wet-sieve size; and

(c) subjecting the unseparated particles of larger than about 50 microns, wet-sieve size, repeatedly to the milling effected substantially solely by interparticulate collision, at a temperature of less than about 200°F.

2. Ultrafine polytetrafluoroethylene adapted for molding precision parts and thin sheeting comprising

porous non-fibrous particles with rounded countours having

a particle size, wet sieve, no greater than 50 microns,

said polytetrafluoroethylene material having

a distribution function of no greater than about .40,

a sub-sieve size of no greater than about 5.0 microns,

a ratio of wet-sieve size to sub-sieve size in the range of about 2 to about 10;

having, upon molding to a zero void content at 6,000 psi,

an unsintered flex strength of at least 860 psi; and

having, after sintering,

a tensile strength of no less than about 4000 psi,

a percent elongation of no less than about 300,

an anisotropic expansion factor of no greater than about 1.13,

a dielectric strength of no less than about 1200 volts per mill,

a surface roughness of no greater than about 82 microinches at 500 psi and no greater than 32 microinches at 2000 psi and

a percent void content of no greater than 0.1% at pressures greater than 2000 psi.

The Rejections

The references relied on are:

Thomas et al. 2,936,301 May 10, 1960

Wallace 3,178,121 Apr. 13, 1965
Filed Apr. 24, 1962

The examiner rejected all claims now appealed "as indefinite under 35 U.S.C. 112," reasoning that, "If a product is to be claimed, it must be defined in terms of its own properties" and that "Applicants' [sic] recitation of an unsintered flex strength is not *** indicative of the properties of the PTFE powder, rather of the unsintered premolded article the powder will be used for." He additionally rejected claims 1, 2, 4-8, and 15-18 as unpatentable over Thomas under 35 U.S.C. 102 on the ground that "These claims are not considered to define over powder G of Thomas et al. in that unsintered flex strength does not define the PTFE claimed" and all claims as unpatentable over Thomas under 35 U.S.C. 103 on the ground that

It would be obvious to one skilled in the art to employ any mill, including a "Jet-O-Mizer"¹ to prepare the powdered PTFE products of Thomas et al. Applicants' [sic] affidavit does [not] present any significant results that would refute this contention. Routine experimentation by one skilled in the art would lead to the use of any air mill to grind PTFE in view of the fact that Thomas et al. disclose air mill grinding of PTFE and more particularly to a "Jet-O-Mizer" admitted by applicant to be an old milling device.

The board affirmed all three rejections. However, it advanced what we consider to be three separate rationales for the section 112 rejection. The first, which it denominated "The more important point," was that the unsintered flex strength recitation is "directed at a result in the preform that is obtainable from the claimed powder upon forming it" and is therefore "Obviously *** not helpful

¹ Appellant's specification discloses that a mill of the type employed in his process is commercially available under the trade name "Jet-O-Mizer."

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in defining the particulate composition or the method for producing it." Second, even if such recitation might be permissible as a last resort when the product could not otherwise be identified,

*** the characteristics of the composition which contribute to the resulting flex strength and the steps of the process used in producing it are all physical or mechanical, presenting no apparent difficulties in direct identification *** [and] thus require no resort to indirect modes of identification.

Finally, the flex strength limitation is indefinite because it "fails to recite the temperature of molding and the compositional characteristics of the material molded, which obviously will profoundly affect the preform strength."

As to the prior art rejections, the board affirmed both the section 102 and section 103 rejections without clearly distinguishing between them. However, it would seem that the board, like the examiner, first determined the flex-strength recitation to be impermissible, thereafter ignored it, and found everything else to have been anticipated by Thomas. As far as it considered the possibility that appellant's product and process were "not identically disclosed or described" in Thomas, it focused on the degree of interparticulate collision in appellant's mill and the mill disclosed in Thomas, which is a characteristic on which appellant expressly *did not* predicate patentability, and ignored sequential versus simultaneous classification, the characteristic on which appellant *did* rely for patentability. Additionally, the board questioned the sufficiency of appellant's comparisons, which indicated that a flex strength of 828 psi was the maximum obtainable by the method disclosed in Thomas in contrast to the minimum of 860 psi recited in appellant's claims, but held that

*** even assuming a valid comparison in all respects, a difference between 828 and 860 in the "unsintered flex strength" would hardly have been an unobvious one in the use of an apparatus more effective in the degree of interparticulate reduction achieved.

Opinion

The Section 112 Rejection

The principal rationale for the section 112 rejection was simply "that unsintered flex strength is a property of compacted preforms made from PTFE powder rather than a property of the powder itself, and that only properties of the powder, as a powder, could be used in defining the powder claimed. Appellant argues that the powder's *capability* of being compacted into a preform having at

least the specified "unsintered flex strength" of the preforms is a property of the powder which may be used to define the powder.

[1] The first sentence of the second paragraph of 35 U.S.C. 112 requires only that claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity." In re Moore, 58 CCPA ___, ___ F.2d ___, 169 USPQ 236, 238 (Mar. 31, 1971). In the absence of evidence to the contrary, we will assume, as we said in Moore, that what the claims define is what the applicant *regards* as his invention. If those skilled in the art can tell whether any particular PTFE powder is or is not within the scope of a claim, the claim fulfills its purpose as a definition. As we remarked recently in reversing a section 112 rejection made on the ground that particular language was "functional" and thus "indefinite," "we are unable to see merit in any proposition which would require the denial of the claim *solely* because of the *type* of language used to define the subject matter for which patent protection is sought." In re Swinehart, 58 CCPA ___, n. 4, 439 F.2d 210, 169 USPQ 226, 228 (Mar. 31, 1971). See also In re Wakefield, 57 CCPA 959, 967, 422 F.2d 897, 904, 164 USPQ 636, 641 (1970) (holding the scope of a claim to be definite "because each recited limitation is definite").

[2] In this case, it seems to us that those skilled in the art will be in no uncertainty concerning what subject matter falls within the scope of the claims. The claims in question recite essentially that the PTFE particles have, upon pressure molding to a zero void content at 6,000 psi, an unsintered flex strength of at least 860 psi. It is clear that PTFE particles which exhibit an unsintered flex strength of less than 860 psi, when subjected to such compression, do not fall within the scope of the claims even if they meet the other claim requirements, while those that exhibit an unsintered flex strength of 860 psi or more when so compressed, and meet other requirements, do. The mechanics of determining the unsintered flex strength of any given batch of PTFE particles are set forth in the specification, and they do not appear to require unreasonable effort. Accordingly, we hold that the challenged language is not fatally defective *solely* because it recites a property which can be measured only after the PTFE powder has been compacted into a preform.

[3] However, the board also reasoned that the flex strength limitation is indefinite because it does not contain "the temperature of molding and the compositional characteristics of the material molded, which obviously

will profoundly affect the preform strength." Appellant has argued that "in the art, unless a temperature is specified it is generally understood that room temperature is intended." If this is so, of course, the claims should be read as though the room-temperature limitation were expressly contained therein. However, appellant did not ask for an opportunity to submit evidence supporting the above assertion, and we will not take judicial notice of its accuracy. Nevertheless, we cannot agree with the board that the omission of the temperature of molding² renders the claims indefinite. Even if it is not true, as appellant asserts, that it is generally understood in the art that omission of temperature from such a recitation indicates that room temperature is intended and the claims are therefore broader than they otherwise would be, breadth is not to be equated with indefiniteness, as we have said many times.

The Prior Art

Thomas discloses PTFE in ultrafine, fibrous form and a process for preparing this product by comminuting commercially available PTFE powder in a rotary blade type grinding and classifying apparatus. To demonstrate the superiority of their particulate PTFE over the prior art, Thomas et al. compare their product to, among others, particulate PTFE "obtained by subjecting *** [a commercial grade of PTFE granular powder] to the disrupting action of high velocity gas jets in a 'Micronizer'." According to Thomas, the result is a powder which "can be readily leveled and compressed, but [which] yields fragile preforms."

The examiner's "use of the Wallace patent," according to the board, was "merely explanatory of the [reference to a] 'Micronizer'" in the above quotation. A "Micronizer," as described in Wallace, is a fluid energy mill which "has a circular disc-shaped working chamber in which both grinding and size-classifying steps are carried out simultaneously."

The Section 102 Rejection

As above mentioned, the basis of both the examiner's rejection under 35 U.S.C. 102 and the board's affirmance thereof seems to have been that since the unsintered flex strength recitation in appellant's product claim is improper it can be ignored and that, with the

² We do not understand the implication in the board's opinion that the claims omit "the compositional characteristics of the material molded." On the contrary, the claims seem to set forth "the compositional characteristics of the material molded" in great detail.

unsintered flex strength recitation out of the way, what was left did not "define over" the Micronizer-prepared powder disclosed in Thomas. In this respect, the section 102 rejection in this case is not unlike the section 103 rejection which we reversed in *In re Wilson*, 57 CCPA 1029, 424 F.2d 1382, 165 USPQ 494 (1970), and is unsupportable for the same reason: "All words in a claim must be considered in judging the patentability of that claim against the prior art" (emphasis added). *Id.* at 1032, 424 F.2d at 1385, 165 USPQ at 496. Moreover, for reasons we have already set forth, we see nothing improper about appellant's recitation of unsintered flex strength as one of the properties of the powder he claims.

Of course, Thomas does not quantify the unsintered flex strength of preforms made from the PTFE powder he milled with a Micronizer air mill, but appellant has submitted evidence, which we will consider more fully in the next section, proving that the unsintered flex strength of Thomas's air-milled powder could not have been as high as the unsintered flex strength recited in his claims. Accordingly, we will not affirm a section 102 rejection on the evidence in this case.³

The Section 103 Rejection

The logic of the rejection under 35 U.S.C. 103 was (1) that, since Thomas disclosed that commercially available PTFE powder could be further comminuted prior to molding and sintering either in some form of hammer mill or in a Micronizer air mill, it was *prima facie* obvious to use any prior art air mill for the same purpose and (2) that appellant's evidence of the superiority of the particular type of prior-art mill he used did not rebut the *prima facie* case. We do not understand appellant to controvert the first step in this reasoning, but he does vigorously assert that his affidavit evidence together with the showing in his application is sufficient to overcome the inference of obviousness to be drawn from the similarity of his process and product to the process and product disclosed in Thomas.

Appellant's application and affidavit compare ultrafine PTFE powder prepared in a

³ Appellant has also pointed out that the rejection under 35 U.S.C. 102 of claims 1, 6-8, and 15-18 is not sound because these process claims recite that the milling is carried out in *sequential steps*, whereas in a Micronizer air mill, grinding and classification take place *simultaneously* in the same zone. Whether this difference is sufficient to make appellant's invention as recited in these claims non-obvious in view of the prior art will be discussed in the next section, but appellant's sequential process is clearly not "identically disclosed or described" in Thomas because of that difference.

[4] As to the number of runs, we note that Example III in appellant's specification sets forth the results of six runs which were made under conditions which appellant swore in his affidavit were, in his opinion, "suitable for preparing a milled PTFE product with good properties, particularly with a property of high unsintered flex strength" and that Table II in the affidavit itself sets forth the results of three runs in which appellant swore that he "attempted to maximize the unsintered flex strength of the resulting 'Micronized' PTFE product * * *." In this ex parte action, too much should not be required of an applicant to rebut the Patent Office's mere suspicions, based on no suggestion in the prior art of record, that some other combination of process limitations might result in higher unsintered flex strength. We accept appellant's evidence as establishing that his invention enables those skilled in the art to produce PTFE preforms of unsintered flex strength greater than the strongest preforms obtainable with the prior art method.

The final question is whether the difference shown is sufficient to establish non-obviousness. Appellant's evidence indicates that, by using an air mill which sequentially grinds and then classifies, he has been able to produce PTFE preforms having an unsintered flex strength of as much as 1100 psi, but his product claims encompass all ultrafine PTFE powders which, in addition to meeting the numerous other claim criteria, have an unsintered flex strength of over 860 psi. The difference between the claim lower limit of 860 psi and the maximum appellant was able to obtain using prior art techniques is only a little less than 4%. However, the evidence clearly indicates that an increase in unsintered flex strength is of great practical utility in the PTFE molding art, since weakness in prior art preforms led to cracking on transportation from the mold to the sintering furnace, causing extensive scrap reworking. Under the circumstances, appellant having demonstrated substantial improvement in unsintered flex strength due to his invention and the prior art failing to show how to attain even the minimum encompassed by the claims, we think he has established unobviousness. Compare *In re Fisher*, 57 CCPA 1099, 427 F.2d 833, 166 USPQ 18 (1970).

Accordingly, we reverse.

Court of Customs and Patent Appeals

In re FISHER

No. 8454

Decided May 13, 1971

PATENTS

Particular patents—Motor

Fisher, Vibratory Motor, claims 9, 11, 12, 14, 17, 29, and 30 of application allowed.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Hardin Y. Fisher, Serial No. 363,561, filed Apr. 29, 1964; Patent Office Group 210. From decision rejecting claims 9, 11, 12, 14, 17, 29, and 30, applicant appeals. Reversed; Baldwin, Judge, concurring with opinion; Almond, Judge, dissenting with opinion.

LLOYD L. ZICKERT and KINZER, DORN & ZICKERT, both of Chicago, Ill., for appellant.

S. WM. COCHRAN (R. V. LUPO of counsel) for Commissioner of Patents.

Before RICH, ALMOND, BALDWIN, and LANE, Associate Judges, and FORD, Judge, United States Customs Court, sitting by designation.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 9, 11, 12, 14, 17, 29, and 30, all remaining claims in appellant's application serial No. 363,561, filed April 29, 1964, for a "Vibratory Motor." We reverse.

The Invention

The invention relates to the kind of vibratory motor used in hand-held massagers, sanders, clippers, and the like. Appellant claims a motor which employs conventional alternating "house" current to impart vibratory motion to the spring-mounted armature of an E-shaped electromagnet. This vibrating armature may be mechanically connected to various workpieces, which will then reciprocate as the armature vibrates. Figure 8 of the specification, said to show structure useful as a hair clipper motor, in which 72 is the spring-mounted armature and 21A is the electromagnet having coil 71, is illustrative. The nub of the invention is the provision on the armature of one or more "wraparound" extensions such as 77 and 78¹ which overlap

¹ The numeral 78 at the left in Fig. 8 is a duplication made in error; the numeral 78 referred to here

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Court of Customs and Patent Appeals

In re Skoll

No. 75-547 Decided Oct. 23, 1975

PATENTS

1. Claims — Indefinite — Chemical (§20.553)

Claim's reference to "organic and inorganic acids" is not indefinite, despite large number of substances within class, and does not give rise to 35 U.S.C. 112, second paragraph rejection.

2. Words and phrases (§70.)

"Hydrolysis" is chemical reaction of water in which bond in reactant other than water is split and hydrogen and hydroxyl are added with formation of two or more new compounds, any decomposition reaction caused by water, and chemical reaction in which water reacts with another substance to form one or more new substances through splitting of water molecule into ions.

3. Claims — Indefinite — Chemical (§20.553)

Words and phrases (§70.)

Person of ordinary skill in art would be aware that "hydrolyzed carbohydrate" means carbohydrate that has reacted with water; term "water soluble hydrolyzed carbohydrate" is not of uncertain scope.

4. Patentability — Anticipation — Combining references (§51.205)

General rule applied to rejection based on combination of references is that references may be combined to show that claim is unpatentable, but they may not be combined indiscriminately.

5. Patentability — Anticipation — Knowledge of prior art presumed (§51.215)

Person with ordinary skill in art is presumed to be aware of references whose disclosures are directed to same technological field as claimed subject matter.

6. Patentability — Evidence of — In general (§51.451)

Patentability — Invention — In general (§51.501)

Expected beneficial results are evidence of obviousness just as unexpected beneficial results are evidence of unobviousness.

7. Claims — Broad or narrow — Markush type — Chemical (§20.2053)

Estoppel — Patent Office procedure (§35.25)

Claim's presentation of Markush group consisting of gluconic acid, glucono delta lactone, and water-soluble salts of gluconic acid, is representation that group's elements are equivalents for purposes of claimed invention, barring applicant from arguing otherwise.

8. Patentability — Evidence of — In general (§51.451)

Patentability — Invention — In general (§51.501)

Quantum of evidence required to establish unobviousness depends on strength of obviousness showing made by prior art.

Particular patents — Plating

Skoll, Method of Electroless Plating, rejection of claims 10-13 and 15 affirmed; rejection of claim 14 reversed.

Appeal from Board of Appeals of the Patent and Trademark Office.

Application for patent of Merceline L. Skoll, Serial No. 152,412, filed June 11, 1971. From decision rejecting claims 10-15, applicant appeals. Modified.

Glenn O. Starke, Milwaukee, Wis., for appellant.

Joseph F. Nakamura (Gerald H. Bjorge, of counsel) for Commissioner of Patents and Trademarks.

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

Lane, Judge.

This is an appeal from the decision of the Patent and Trademark Office Board of Appeals affirming the examiner's rejection of claims 10-15, all of the claims in application serial No. 152,412, filed June 11, 1971 for a "Method of Electroless Plating." We affirm in part and reverse in part.

Background

The subject matter of the claims is an aqueous solution for electroless plating. The solution contains a water-soluble metal salt, a water-soluble hydrolyzed carbohydrate, and a gluconic acid component selected from the group consisting of gluconic acid, glucono delta lactone, and water-soluble

salts of gluconic acid. The metal salt, which is the source of the metal ions to be plated, may be selected from a wide variety of water-soluble metal salts including salts of gold, silver, copper, etc. The water-soluble carbohydrate may be a monosaccharide, a disaccharide, or a polysaccharide. The carbohydrate is present in a concentration greater than 5 grams per 100 milliliters of the solution. Suitable water-soluble salts of gluconic acid include sodium gluconate, potassium gluconate, and the like. The solution may optionally contain an additional acid component. The solution may also optionally contain phytol or guanylic acid.

It has been found by appellant that by using a relatively large concentration of hydrolyzed carbohydrate in combination with a gluconic acid component, an increased rate of deposition of metal ions is achieved. The addition of phytol or guanylic acid to the plating solution further increases the rate of deposition of metal ions. The optional additional acid component is said to aid in obtaining special colors, tones, etc.

Claim 10 is representative:

10. An electroless plating solution for plating a base material, consisting essentially of a water solution having dissolved therein, a water soluble metal salt, an acidic component selected from the group consisting of gluconic acid, glucono delta lactone, and water soluble salts of gluconic acid, and a water soluble hydrolyzed carbohydrate, said carbohydrate being present in a concentration greater than 5 grams per 100 ml of said solution and said solution having a pH in the range of 0.5 to 7.0.

Claims 11-15 are dependent on claim 10.

Rejections

The patents relied upon by the board are:

Gostin et al. (Gostin)	3,032,436	May 1, 1962
Robinson	3,230,098	January 18, 1966

Gostin discloses an aqueous solution for gold plating metallic articles by an electroless deposition process which is said to deposit a gold plate rapidly and uniformly. The plating solution contains a water-soluble gold salt, a reducing agent which may be glucose or another sugar, a buffer which may be an ammonium salt of a carboxylic acid, and a weak acid or base sufficient to produce the desired pH. It is disclosed that the amount of gold deposited is a function of the temperature of the plating solution, the concentration of reducing agent, and the pH of the bath.

Robinson discloses an aqueous solution for gold plating metallic articles by an electroless deposition process which is said to deposit a gold film of uniform thickness and good adherence. The plating solution contains a water-soluble gold salt, an ammonium buffering agent, and an organic chelating agent. The ammonium buffering agent may be the ammonium salt of a weak acid and may, for example, be ammonium gluconate. In addition to regulating the pH of the plating solution, the ammonium buffering agent may serve to accelerate the rate of plating, i.e., to increase the rate of deposition of metal ions, by attacking the metal surface to be plated.

The examiner rejected the claims as obvious in view of Gostin taken together with Robinson under 35 USC 103, and the board affirmed. In response to the examiner's rejection under 35 USC 103, appellant submitted an affidavit setting forth a series of tests illustrating the improved results achieved by using the claimed metal plating solution. The examiner found the affidavit insufficient to overcome the prior art because the tests discussed in the affidavit were not commensurate with the scope of the claims. The board examined the affidavit and found that it was not convincing.

The examiner also rejected claims 10 through 15 as indefinite and of uncertain scope under 35 USC 112, second paragraph, and the board affirmed. The examiner specifically objected to the expressions "water soluble hydrolyzed carbohydrate" and "organic and inorganic acids" (appearing only in claim 15*).

Opinion

Section 112

[1] We first consider the expression "organic and inorganic acids," which is said to be indefinite and of uncertain scope. We cannot agree. Although there are undoubtedly a large number of acids which come within the scope of "organic and inorganic acids," the expression is not for that reason indefinite. We see no reason to believe that the public would be confused as to what *subject matter* is circumscribed by appellant's claim. In re Kroekel, 504 F.2d 1143, 183 USPQ 610 (CCPA 1974).

* Claim 15. The plating solution of claim 10, wherein the solution also contains a second acid component separate from the first acid component and selected from the group consisting of organic and inorganic acids, the total acid concentration of said solution being greater than 1 gr. per ml of solution.

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Whether or not a substance comes within the class of "organic and inorganic acids" is rendered no less certain by the large number of substances within the class. The board's comment that it is not clear that all acids will give the desired results is relevant to a rejection under 35 USC 112, first paragraph, not 35 USC 112, second paragraph. There is no first paragraph rejection in this case. We conclude that the expression "organic and inorganic acids" is not indefinite.

With regard to "water soluble hydrolyzed carbohydrate," the board noted that the specification disclosed many carbohydrates but found no adequate reference in the specification for "hydrolyzed carbohydrates." The board held that the claims were of uncertain scope as to this expression. It is appellant's position that the controversy centers on the meaning of the term "hydrolyzed." We agree. The word appears in claim 10 in the following context: "An electroless plating solution * * * consisting essentially of a water solution having dissolved therein * * * a water soluble hydrolyzed carbohydrate * * *"

In her specification appellant makes the following statements:

The carbohydrate is preferably an oligo-saccharide which is defined as a compound that, on complete hydrolysis, gives one or more monosaccharides in relatively small numbers per molecule.

When added to the aqueous plating solution, the carbohydrate, over a period of time, will hydrolyze, and the hydrolyzation, it is believed, acts to shorten the effective length of the carbon chains in the carbohydrate and increase the Angstrom potential, thereby increasing the rate of deposition or throwing power of the plating bath. The time required to achieve hydrolyzation depends on various factors such as the quantity or volume of the bath, the concentration of the carbohydrate and the agitation of the bath. Large volumes, such as a 55 gallon drum, may require a period, with agitation, of 48 hours to complete hydrolyzation of the carbohydrate. With smaller volumes hydrolyzation can be accomplished in 3 or 4 hours or more.

[2] In her brief appellant makes the following statements:

"Hydrolyzed" refers to the act of undergoing hydrolysis and "hydrolysis" is defined as:

"A chemical reaction of water in which a bond in the reactant other than water is split and hydrogen and hydroxyl are added with the formation of two or more new compounds." Webster's Third International Dictionary.

Similarly, "hydrolysis" is defined in Chemical Dictionary, Hackl [sic], as:

"Any decomposition reaction which is caused by water."

We agree with these two definitions of "hydrolysis" and would add a third from The Condensed Chemical Dictionary 456 (8th ed. 1971):

A chemical reaction in which water reacts with another substance to form one or more new substances. This involves splitting of the water molecule into ions. Examples are the conversion of starch to glucose by water in the presence of suitable catalysts; the conversion of sucrose (cane sugar) to glucose and fructose by reaction with water, in the presence of an enzyme or acid catalyst; the conversion of natural fats into fatty acids and glycerin by reaction with water in one process of soap manufacture; and the reaction of the ions of a dissolved salt to form various products, such as acids, complex ions, etc.

[3] The solicitor interprets the board's statement regarding "hydrolyzed carbohydrates" as meaning that the board felt that the nature of the hydrolyzed carbohydrates, or the extent to which the polysaccharides had been hydrolyzed, had not been described in full, clear, concise, and exact terms. A person of ordinary skill in the art would be aware that the term "hydrolyzed carbohydrate" means a carbohydrate which has reacted with water. We find that the "water soluble hydrolyzed carbohydrate" is described in appellant's specification in such full, clear, concise, and exact terms that its meaning can be definitely determined.

We conclude that the expression "water soluble hydrolyzed carbohydrate" is not of uncertain scope. We reverse the rejection of all of the appealed claims under 35 USC 112, second paragraph.

Section 103

The claims were further rejected as obvious in view of Gostin taken together with Robinson under 35 USC 103.

[4] We agree with appellant that the general rule applicable to a rejection based on a combination of references was stated by

this court in *In re Schaffer*, 43 CCPA 758, 761-62, 229 F.2d 476, 479, 108 USPQ 326, 328-29 (1956):

[R]efere[n]ces may be combined for the purpose of showing that a claim is unpatentable. However, they may not be combined indiscriminately, and to determine whether the combination of references is proper, the following criterion is often used: namely, whether the prior art suggests doing what an applicant has done * * *. [I]t is not enough for a valid rejection to view the prior art in retrospect once an applicant's disclosure is known. The art applied should be viewed by itself to see if it fairly disclosed doing what an applicant has done.

[5] With this criterion in mind, we first consider whether the Gostin and the Robinson references were properly viewed together. Both references disclose gold plating metallic articles by an electroless deposition process, i.e., by simply immersing the article to be plated in the plating solution (without applying any electrical potential as in the case of electrolytic plating). Thus, both disclosures are directed to the same technological field as the claimed subject matter. A person of ordinary skill in that art is presumed to be aware of these references:

It is an object of the Gostin process to deposit a gold plate *rapidly* on metal objects immersed in the plating solution. The Gostin plating solution differs from the subject matter of claim 10 in that no specific amount of sugar is disclosed in Gostin, and further in that there is no disclosure of an acidic component selected from the group consisting of gluconic acid, glucono delta lactone, and water-soluble salts of gluconic acid in Gostin. Gostin does disclose that it is desirable to maintain the pH of the plating solution nearly neutral and that for this purpose a buffering agent is added to the solution. Although the preferred buffering agent is ammonium citrate, ammonium salts of other similar carboxylic acids may be used.

[6] Robinson discloses that an ammonium buffering agent, i.e., the ammonium salt of a weak acid, may serve in his plating solution to *accelerate the plating* by attacking the surface of the article to be plated. Robinson discloses suitable ammonium buffering agents to include ammonium citrate, ammonium tartrate, ammonium borate, ammonium gluconate, or ammonium acetate. We believe that Robinson would suggest to one of ordinary skill in this art the desirability of substituting any of

these ammonium buffering agents as the ammonium salt of a carboxylic acid in the plating solution of Gostin. The desirability of such a substitution comes from the Robinson reference itself. Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected beneficial results are evidence of unobviousness. *In re Skoner*, 517 F.2d 947, 950, 186 USPQ 80, 82 (CCPA 1975); *In re Gershon*, 54 CCPA 1066, 1069, 372 F.2d 535, 537, 152 USPQ 602, 604 (1967).

To rebut this evidence of obviousness, appellant submitted an affidavit in an attempt to prove that the amount of carbohydrate required by the claims is essential, that the gluconic acid component cannot be replaced by either ammonium citrate or by an inorganic acid such as hydrochloric acid, and that the combination of carbohydrate and gluconic acid component is essential. With regard to the alleged criticality of the amount of carbohydrate, the board noted that Test VIII gave a copper plating of 0.5 mil thickness when 50 grams of sucrose was employed (the minimum amount required by the claims), while Test V gave a copper plating of 0.4 mil thickness when 10 grams of sucrose was employed. We agree with the board in finding the difference in these two platings insignificant.

Test VIII	Test V
100 g copper sulfate	100 g copper sulfate
500 ml 50% ammonium gluconate	500 ml 50% gluconic acid
500 ml water	500 ml water
50 g sucrose	10 g sucrose

[7] Appellant, in her brief, argues that this comparison is unreasonable because gluconic acid is expressly disclosed in her specification (and therefore preferred), whereas ammonium gluconate is not expressly disclosed (and therefore not preferred). Appellant admits that ammonium gluconate, a water-soluble salt of gluconic acid, is within the scope of the claims. We find appellant's argument lacking in merit. It will be remembered that the Markush group in claim 10 is the group consisting of gluconic acid, glucono delta lactone, and water-soluble salts of gluconic acid. By the presentation of this Markush group, appellant has made a representation that for the purpose of the claimed invention the elements of the group are equivalents. Having made the representation that water-soluble salts of gluconic acid are equivalent to gluconic acid for the purpose

ing agents as the boxylic acid in the n. The desirability comes from the itself. Expected ence of obviousness just as unexpected vidence of unob- 517 F.2d 947, 950, (PA 1975); In re 6, 1069, 372 F.2d 604 (1967).

of obviousness, affidavit in an ie amount of car- ie claims is essen- d component can- ammonium citrate ch as hydrochloric abination of car- acid component is to the alleged of carbohydrate, Test VIII gave a hickness when 50 employed (the d by the claims), plating of 0.4 mil s of sucrose was the board in find- two platings in-

Test V

100 g copper sulfate
500 ml 50% gluconic acid
500 ml water
10 g sucrose

rief, argues that sonable because disclosed in her fore preferred), onate is not ex- therefore not limits that am- er-soluble salt of he scope of the s argument lack- embered that the is the group con- ucono delta lac- alts of gluconic of this Markush a representation laimed invention are equivalents. sentation that ionic acid are for the purpose

of the claimed plating solution, appellant may not now argue that these two elements are not equivalents. We conclude that the board's comparison of Test VIII with Test V was reasonable and that the affidavit fails to support appellant's allegation that the amount of carbohydrate required by the claims is critical.

[8] The affidavit was also presented by appellant to demonstrate that ammonium citrate cannot be substituted for ammonium gluconate in the claimed plating solution. The affidavit, however, presents only one comparison.

Test VIII

100 g copper sulfate
500 ml 50% ammonium gluconate
500 ml water
50 g sucrose

Test IX

100 g copper sulfate
500 ml 50% ammonium citrate
500 ml water
50 g sucrose

As noted above, Test VIII gives a copper plating of 0.5 mil thickness, while Test IX gives a spotty plating said to be of no commercial value. We agree with the board that the affidavit demonstrates that ammonium citrate cannot be substituted for ammonium gluconate in copper plating solutions. But none of the claims is limited to copper plating solutions. The references suggest that ammonium gluconate is equivalent to ammonium citrate in gold plating solutions. Appellant has presented no evidence that this suggestion of the references is not correct. Appellant's claimed plating solution may contain any water-soluble metal salt. The quantum of evidence required to establish obviousness will depend upon the strength of the showing of obviousness made by the prior art. In re Saunders, 58 CCPA 1316, 444 F.2d 599, 170 USPQ 213 (1971). In the facts of this case, where appellant has failed to present evidence to rebut the specific suggestion of the prior art, we conclude that the affidavit is inadequate to overcome the showing of obviousness made by the prior art. We will, therefore, affirm the rejection of claim 10 under 35 USC 103.

Claims 11, 12, and 13 add further limitations to the carbohydrate component of the plating solution. As we have already discussed, the prior art teaches the presence of a carbohydrate component in the plating solution and there is no evidence that the concentration of carbohydrate is critical. Appellant's specification does not disclose any critical difference between the use of an oligosaccharide rather than any other water-soluble carbohydrate. We will,

therefore, affirm the rejection of claims 11, 12, and 13 under 35 USC 103.

Claim 14 requires the addition of phytol or guanylic acid to the plating solution. There is no disclosure in the prior art of either phytol or guanylic acid. Because there is no disclosure in the prior art, the rejection of claim 14 under 35 USC 103 must be reversed for lack of evidence of obviousness.

Claim 15 requires the addition of a second acid component in addition to the gluconic acid component. This second acid may be any organic or inorganic acid. Gostin discloses the addition of an acid to regulate the pH of the plating solution. Since claim 15 does not limit the second acid to any specific function, it may regulate the pH of the plating solution. We will, therefore, affirm the rejection of claim 15 under 35 USC 103.

Conclusion

The decision of the board affirming the rejection of claims 10, 11, 12, 13, and 15 is affirmed. The decision of the board affirming the rejection of claim 14 is reversed.

Court of Customs and Patent Appeals

In re Orion Research Incorporated

No. 75-540 Decided Oct. 23, 1975

TRADEMARKS

1. Marks and names subject to ownership — Service marks (§67.525)

Registration — Service marks (§67.761)

Trade literature indicating that guarantee applies only to applicant's goods and for limited time, and lack of evidence that applicant separately offers, charges for, or promotes guarantee or that goods are sold without it, cumulatively indicate that applicant merely guarantees its own goods rather than provides Lanham Act service for which registration or mark could be obtained; guarantee of warranty does not constitute separate service.

2. Class of goods — In general (§67.201)

Marks and names subject to ownership — Service marks (§67.525)

Registration — Service marks (§67.761)

Although repair can be Lanham Act Section 45 service, alleged "service" that is no

Opinion

Appellant CTS Corporation opposed registration on the basis of registration of the letters "CTS" for volume controls, tone controls and switches, for use in connection with radio receiving and amplifying equipment;¹ potentiometers of the variable resistance type used in radios, rheostats, tone control switches, selector switches, and snap switches;² and potentiometers used for measuring.³ The record shows that appellant has also used the letters "CTS" for laminated fiber insulating sheets since 1965.

This case turns upon whether or not purchasers might reasonably be likely to believe that goods for which appellee seeks registration emanate from appellant. *Hollywood Water Heater Co. v. Hollymatic Corp.*, 47 CCPA 782, 274 F.2d 679, 124 USPQ 452 (1960); *J.C. Hall Co. v. Hallmark Cards, Inc.*, 52 CCPA 981, 340 F.2d 960, 144 USPQ 435 (1965). The goods for which appellee seeks registration are described in appellee's trademark application as "thermal insulated panel walls."

It appears from the board's opinion that appellee first filed its application to register "CTS" for *framing structures*. Thereafter, pursuant to a suggestion from the examiner, the identification of goods in appellee's application was amended to read "thermal insulated panel walls," although it was stated by appellee that the original identification of its goods " * * * was believed to be accurate and representative of the goods of applicant * * *." In its opinion the board also expressed the view that appellee's original description of its goods was more accurate than the amended one. The board then stated: "Accordingly, should applicant ultimately prevail herein, it should file an appropriate amendment to its description of goods prior to the issuance of its registration."

[1] Appellant and appellee agree that the goods which appellee sells are aluminum or metal framing systems which form, when assembled with thermal insulated panels (such as glass or the like), thermal insulated panel walls which are mounted upon the face of a building structure. Appellee does not sell the thermal insulated panels. We agree with appellee that the original identification

of its goods as "framing structures" was more accurate and representative of the goods. However, in view of the requirement in section 1(a)(1) of the Trademark Act of 1946 (15 USC 1051(a)(1)) that the description of goods in an application for registration be *specific*, we consider it proper in this case to construe appellee's description of its goods in the manner most favorable to appellant. *David Crystal, Inc. v. Soo Valley Co.*, 471 F.2d [3] 1245, 176 USPQ 326 (CCPA 1973). In our view, the term "thermal insulated panel walls," is broad enough to reasonably include laminated fiber insulating sheets such as those which appellant has sold since 1965.

[4] In view of our interpretation of appellee's term "thermal insulated panel walls" we find likelihood of confusion between use of the identical letters "CTS" as applied to the respective goods. We emphasize that this conclusion is required by appellee's inapt identification of its goods as "thermal insulated panel walls." Under section 7(b) of the Trademark Act of 1946 (15 USC 1057(b)), a certificate of registration of a mark upon the Principal Register is *prima facie* evidence of the registrant's exclusive right to use the mark in commerce in connection with the goods specified in the certificate. In the present case, a registration to appellee would evidence, *prima facie*, appellee's exclusive right to use its mark on goods upon which it does not use its mark. See *American Throwing Co. v. Famous Bathrobe Co.*, 45 CCPA 737, 250 F.2d 377, 116 USPQ 156 (1957); *Shoe Corp. of America v. Juvenile Shoe Corp. of America*, 46 CCPA 868, 266 F.2d 793, 121 USPQ 510 (1959).

The decision of the Trademark Trial and Appeal Board is reversed.

Court of Customs and Patent Appeals

In re Mercier

No. 74-528 Decided May 15, 1975

PATENTS

1. Patentability — Anticipation — Modifying references (§51.217)

All relevant teachings of cited references must be considered in determining what they fairly teach to one having ordinary skill in art.

¹ Registration No. 304,736, issued July 18, 1933.

² Registration No. 507,559, issued March 15, 1949.

³ Registration No. 663,452, issued June 24, 1958.

as "framing structure and representation. However, in view of section 1(a)(1) of the Act of 1946 (15 USC description of goods in application must be specific, we construe this case to construe of its goods in the light of the evidence to appellant. David Valley Co., 471 F.2d 26 (CCPA 1973). In thermal insulated panel which is reasonably insulating sheets such appellant has sold since

our interpretation of thermal insulated panel likelihood of confusion critical letters "CTS" respective goods. We conclusion is required identification of its goods insulated panel section 7(b) of the Act (15 USC 1057(b)), a mark upon the prima facie evidence of right to use the connection with the certificate. In the presence to appellee would appellee's exclusive goods upon which it see American Throwrobe Co., 45 CCPA 6 USPQ 156 (1957); ca v. Juvenile Shoe CCPA 868, 266 F.2d 1959).
Trademark Trial and Appeal Board.

and Patent Appeals

Mercier

dated May 15, 1975

Anticipation — In re Mercier

of cited references in determining what having ordinary skill

2. Patentability — Evidence of — Suggestions of prior art (§51.469)

Relevant portions of reference include not only teachings that would suggest particular aspects of invention to one having ordinary skill in art, but also teachings that would lead away from claimed invention.

3. Court of Customs and Patent Appeals — Issues determined — Ex parte patent cases (§28.203)

Statement in applicant's reply brief that distinction between materials lay in fact that one group was subject to side reactions while other was not, is sufficient basis in record presented to Board of Appeals to merit Court of Customs and Patent Appeals' consideration of differences in material of prior art reference and application.

4. Patentability — Invention — Specific cases — Chemical (§51.5093)

Patentability — Substitution of equivalents (§51.65)

Mere known relationship between classes of compounds as disclosed by isolated portion of prior art reference is insufficient to support section 103 rejection; as distinguished from disclosure of equivalents, disclosure of known relationship does no more than teach that it would have been obvious to try, which is insufficient under section 103; mere relationship is insufficient basis for necessary predictability of success to sustain section 103 rejection.

5. Patentability — Invention — Specific cases — Chemical (§51.5093)

Conclusion that applicant's invention would have been nonobvious to one having ordinary skill in art is buttressed by fact that claimed invention is catalytic process.

6. Patentability — Invention — Specific cases — Chemical (§51.5093)

Patentability — Substitution of equivalents (§51.65)

Fact that processing details of claimed invention are substantially identical to those of reference lends nothing to section 103 rejection absent showing that it was obvious to substitute compounds of application for compounds of reference.

7. Patentability — Invention — Specific cases — Chemical (§51.5093)

Patentability — Substitution of equivalents (§51.65)

Adequacy of showing of chemical equivalency must be scrutinized especially

carefully where it is alleged to have been obvious to substitute one starting material for another in catalytic process.

8. Construction of specification and claims — Claim defines invention (§22.30)

If one can determine whether process is within scope of claim, claim fulfills its purpose as definition.

9. Claims — Indefinite — In general (§20.551)

Whether term used in claim is conventional is not necessarily controlling on question of indefiniteness.

Particular patents — Splitting acetals

Mercier, Process for Splitting Acetals and Hemi-acetals, rejection of all claims, reversed.

Appeal from Board of Appeals of the Patent and Trademark Office.

Application for patent of Jules Mercier, Serial No. 708,775, filed Feb. 28, 1968. From decision rejecting all claims; applicant appeals, Reversed; Markey, Ch. J., dissenting with opinion.

Keith V. Rockey, Chicago, Ill. (David R. Murphy, Arlington, Va., of counsel), for appellant.

Joseph F. Nakamura and Jack E. Armore for Commissioner of Patents and Trademarks.

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

Baldwin, Judge.

This appeal is from the decision of the Patent and Trademark Office Board of Appeals affirming the examiner's rejection of all claims remaining in application serial No. 708,775, filed February 28, 1968, entitled "Process for Splitting Acetals and Hemi-Acetals." We reverse.

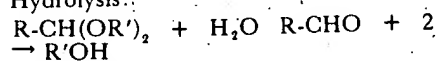
The Invention

Appellant's invention relates to a process for "splitting" acetals and hemi-acetals by either hydrolysis or alcoholysis reactions. The alcoholysis of acetals or hemi-acetals by means of alcohols results in the formation of acetals having alcohol radicals different from those on the original material. The hydrolysis reaction of acetals or hemi-acetals with water results in the formation of the corresponding aldehydes.

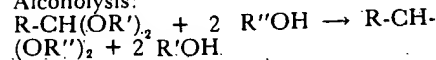
Appellant's specification describes the reactions of the invention as follows:

These reactions can be illustrated by the following equations in which R, R' and R'' can be organic radicals which are the same or different hydrocarbon radicals which may be straight or branched-chain alkyl radicals having from 1 to 12 carbon atoms, such as methyl, ethyl, propyl, isopropyl, butyl, isobutyl, amyl, isoamyl, hexyl, 2-ethyl butyl, heptyl, octyl, isoocetyl, 2-ethyl hexyl, nonyl, isononyl, decyl and dodecyl; alkenyl radicals having from 3 to 12 atoms, such as propenyl, butenyl, hexenyl and allyl, the olefinic linkage of the alkenyl radicals being not in a, b; alicyclic radicals, such as cyclohexyl and methyl cyclohexyl; and aralkyl radicals, such as benzyl. R can also be hydrogen or an aromatic radical, such as phenyl, tolyl and xylyl, the aromatic radical having only one nucleus, the nucleus bearing no more than two alkyl substituents, and the total amount of carbon atoms of the alkyl substituents, if any, being from 1 to 5.

Hydrolysis:



Alcoholysis:



The prior art processes for accomplishing the above-referred to reactions are apparently subject to some difficulties. For example, the removal of one or both of the OR' groups on the acetal may have a tendency to cause polymerization into what the specification refers to as "complex compounds of varying and not accurately defined polymerization degree." The removal of an OR' group apparently can also lead to the formation of undesired highly volatile and explosive ethers. Additionally, use in many of the prior art processes of a strong inorganic acid such as sulfuric acid to catalyze the splitting reaction causes corrosion problems and provides a product which is difficult to separate from the catalyst.

Appellant's process for "splitting" acetals and hemi-acetals is accomplished by passing a homogeneous liquid phase containing the reactant upwardly through a bed of suspended catalyst particles in the form of a sulfonic ion-exchange resin in the acid form.

The specification sets forth the processing details by which the process may be carried out as follows:

Continuous operation may, for example, be performed by passing the liquid reactants heated to reaction temperature

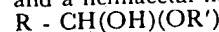
through a reaction zone containing a catalyst and maintained under the pressure required for maintaining the reaction medium or mixture in a liquid state at the operating temperature. One may advantageously employ, inter alia, an inverted cone-shaped reactor through which the reaction medium or mixture flows in an upward direction thereby to maintain the finely divided catalyst in a dispersed or suspended state or in a fluidized state through the liquid phase. [Emphasis added.]

The language of the claims defines the invention in much the same manner as the specification, except that the sulfonic ion exchange catalyst is referred to as a "fluidized catalyst" instead of a catalyst in a "dispersed or suspended state or in a fluidized state through the liquid phase." Claim 16 is representative:

16. A process for splitting acetals and hemi-acetals which comprises passing, a homogeneous liquid reaction mixture comprising a compound selected from the group consisting of an acetal having the formula:



and a hemiacetal having the formula:



wherein R is selected from the group consisting of hydrogen and a hydrocarbon group containing 1-12 carbon atoms and R' is a hydrocarbon group containing 1-12 carbon atoms and a material selected from the group consisting of water and a mixture of alkanol and water, wherein the water constitutes between 5-30% by weight of the reaction mixture, upwardly through a fluidized catalyst, said catalyst being a sulfonic ion exchange resin in acid form, at a temperature of 60° to 140° C. and a pressure sufficient to maintain the reaction mixture in the liquid phase.

The Prior Art Rejection

The following references were relied on:

Enk et al. (Enk)	3,317,593	May 2, 1967
Alheritiere et al. (Alheritiere)	2,980,731	April 18, 1961

The board cited the following as "[g]eneral references of which we take judicial notice":

Webster's Third New International Dictionary, Unabridged, p. 877 (1963).
Kirk-Othmer, Encyclopedia of Chemical Technology, Second Edition, Vol. 9, pp. 398, 399 (1966).
The Condensed Chemical Dictionary, 7th Ed., p. 423 (1966).
Hackh's Chemical Dictionary, 4th Ed., p. 273 (1969).

ion zone containing a maintained under the d for maintaining the or mixture in a liquid ating temperature. One isly employ, inter alia, shaped reactor through on medium or mixture ard direction thereby to luidized catalyst in a dispers- ite or in a fluidized state ase. [Emphasis added.]

he claims defines the in- e same manner as the at that the sulfonic ion ex- ferred to as a "fluidized f a catalyst in a "dis- d state or in a fluidized uid phase." Claim 16 is

for splitting acetals and ch comprises passing a uid reaction mixture ound selected from the of an acetal having the

having the formula:

(¹)
ted from the group con- en and a hydrocarbon 1-12 carbon atoms and rbon group containing i and a material selected nsisting of water and a l and water, wherein the s between 5-30% by tion mixture, upwardly d catalyst, said catalyst n exchange resin in acid ature of 60° to 140° C. fficient to maintain the in the liquid phase.

Art Rejection

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3,317,593 May 2, 1967
2,980,731 April 18, 1961
ed the following as es of which we take

New International Dic- ed, p. 877 (1963).
yclopedia of Chemical nd Edition, Vol. 9, pp.

hemical Dictionary, 7th).
Dictionary, 4th Ed., p.

Perry's Chemical Engineers' Handbook, 4th Ed., §20, pp. 42-52, particularly p. 50 (1963).

The appealed claims were rejected by the examiner over Enk in view of Alheritiere under the provisions of 35 USC 103. Enk teaches a process for the hydrolysis of alkanol derivatives, such as acetals, by means of water in the presence of a static acid exchange catalyst. His specification states:

It is known to crack hydrolyzable organic oxygen compounds such as, for example, esters, acetals or ketals, in the presence of acid catalysts, like mineral acids or cation exchangers, with water, into alcohol and the appropriate organic residue. In all cases the reaction can be carried out only up to the hydrolysis equilibrium. The hydrolysate, in equilibrium, consisting of the starting substance, water, alcohol and a second cracking product which, depending upon the starting substance, is an acid, an aldehyde or a ketone, is then separated into its components.

Alheritiere discloses a process in which a solid catalyst is suspended in an upwardly flowing liquid reaction mixture. The catalyst is thus suspended in a turbulent state in the liquid permitting more efficient mass and heat transfer rates and facilitating reactions involving heterogeneous liquid mixtures. Alheritiere teaches generally that hydrolysis reactions using an ion exchange resin catalyst may be advantageously accomplished by means of his process, but he nowhere specifically discloses the hydrolysis of either acetals or hemi-acetals.

The board agreed with appellant that it was improper for the examiner to combine the two references, "with respect to the inventive contribution of Enk et al.," but upheld the rejection insofar as it was based on "the teachings of Enk et al. as to what was previously known in the art." The board stated:

In view of the teachings in Enk et al. as to the relationship between esters and acetals in hydrolysis by means of cation exchange resins it would clearly be obvious to one skilled in this art to substitute an acetal for the methyl acetate or other esters in Alheritiere et al., thus to anticipate appellant's claimed contribution. The Examiner's rejection will therefore be sustained.

Other Rejections

The appealed claims were further rejected by the examiner as failing to comply with the second paragraph of 35 USC 112, "as

being indefinite in the recitation 'a fluidized catalyst' in claim 16, on which all the other claims depend directly or indirectly." The examiner stated:

In a true fluidized system, a gas is passed upwards through a mass of granular or powdered solid, so that particles are "floated" and the mass resembles a boiling liquid in appearance. See In re Edwards [43 CCPA 884, 232 F.2d 641, 109 USPQ 380 (1956)], 1956 C.D. 264. The term "fluidized" is not appropriate to a system wherein the solids are suspended in a liquid medium.

Sustaining the rejection, the board commented:

The teaching in page 3 of the specification of the catalyst in a dispersed suspended or fluidized state throughout the liquid phase is not the above-cited terminology now incorporated in the claims by an amendment. While the dictionary cited by appellant appears to include a moving liquid to suspend solids to produce a fluidized catalyst it might appear that such a liquid in boiling condition may be intended since the more general definition of a fluidized catalyst is limited to finely divided solid catalysts suspended in a moving gas in such manner that the entire mass acts like a fluid. Webster's and Hackh's Dictionaries, above-cited, as well as Kirk-Othmer's Encyclopedia and Perry's Handbook demonstrate the widespread acceptance of a gas or vapor as the suspending agent. Further as the Examiner has indicated in the decision cited by appellant, In re Edwards, 1956 C.D. 264, the references therein discussed also indicate the term "fluidized catalyst" to be known as applied to gas-suspended solid catalyst particles.

Furthermore, since the term "fluidized catalyst" was added to the claims by amendment, the board sustained the rejection of the claims as lacking antecedent basis in the specification and thus introducing new matter prohibited by 35 USC 132 and Rule 75(d), 37 CFR 1.75(d).

The board went on to find an additional basis for the examiner's rejection of the claims based on the first paragraph of section 112:

[S]ince it is quite apparent that the criticized term encompasses gas suspension of the catalyst which would not appear to be operative in the claimed process, the terminology not only violates 35 U.S.C. 112, second paragraph, in delineating more than that which appellant

considers to be his invention but also fails to find enabling support in the disclosure (paragraph one of this section of the statute). The Examiner's rejection will therefore be sustained.

Opinion

The Prior Art Rejection

[1] Whether appellant's invention is obvious under 35 USC 103 depends at the outset upon the propriety of the board's simultaneous reliance on what Enk says is known in the art and disregard of the rest of Enk's disclosures. We find several difficulties with this analysis. The general statement in Enk that one having ordinary skill in this art is aware that acetals may be cracked with water in the presence of an acid catalyst, "like mineral acids or cation exchangers," lacks any teaching of how the process is accomplished by prior art techniques. What temperatures would be required for the reaction? What was the physical state of the catalyst? Will the reaction proceed in a homogeneous liquid phase, or in a gaseous phase or only in a multi-phase system? These and other questions arise because the board's approach fails to recognize that *all* of the relevant teachings of the cited references must be considered in determining what they fairly teach to one having ordinary skill in the art. In re Meinhardt, 55 CCPA 1000, 1004, 392 F.2d 273, 276, 157 USPQ 270, 272 (1968). See also In re Halley, 49 CCPA 793, 296 F.2d 774, 132 USPQ 16 (1961); In re Van Mater, 52 CCPA 1076, 341 F.2d 117, 144 USPQ 421 (1965).

[2] The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention. See In re Lunsford, 53 CCPA 986, 357 F.2d 380, 148 USPQ 716 (1966).

The board's approach amounts, in substance, to nothing more than a hindsight "reconstruction" of the claimed invention by relying on isolated teachings of the prior art without considering the over-all context within which those teachings are presented. Without the benefit of appellant's disclosure, a person having ordinary skill in the art would not know what portions of the disclosure of the reference to consider and what portions to disregard as irrelevant, or misleading. See In re Wesslau, 53 CCPA 746, 353 F.2d 238, 147 USPQ 391 (1965).

Enk's specification was relied upon by the board to show that organic hydrolyzable oxygen-containing compounds, including es-

ters and acetals, may be cracked "in the presence of acid catalysts, like mineral acids or cation exchangers with water into alcohol and the appropriate organic residue." This disclosure is relevant to the obviousness inquiry, since appellant claims, *inter alia* a process for the hydrolysis of acetals and hemi-acetals in the presence of water and a sulfonic ion-exchange resin catalyst in the acid form. There is, however, additional relevant knowledge made available by the disclosure of Enk within the context of which the isolated teaching ought properly to be considered.

Again referring to the prior art, Enk teaches:

In all cases the reaction can be carried out only up to the hydrolysis equilibrium. The hydrolysate in equilibrium, consisting of the starting substance, water, alcohol and a second cracking product which, depending upon the starting substance, is an acid, an aldehyde or a ketone, is then separated into its components.

Since due to the *unfavorable hydrolysis equilibrium*, which for instance under stoichiometric conditions for methyl acetate means only about 30% conversion — a comparatively large quantity of methyl acetate is present in the hydrolysate which with methanol form an azeotropic mixture in the proportion of about 4:1, the larger part of the methanol can be obtained only in the form of the azeotropic mixture from which it must be separated for instance by extractive distillation * * *. [Emphasis added.]

Enk discloses a process for avoiding this deleterious equilibrium condition which by:

removing both reaction products and retaining the starting substance (the hydrolyte) in the reaction chamber, permits the shift of the equilibrium in the direction of complete hydrolysis and thus make possible an almost 100% transformation without circulation of the starting substrate and without forming an azeotropic mixture, with a single pass. The process is characterized by the fact that the water-containing liquid phase flowing downward in the ion exchanger bed and perhaps containing the second cracking product is used for the extraction of the obtained alcohol, and the starting substance is kept in the rising vapor phase until the transformation is complete.

Enk thus warns that the equilibrium condition for the reaction is to be avoided, and that this may be accomplished by carrying

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out the hydrolysis reaction in a heterogeneous phase system in order to continuously remove the reaction products while maintaining the starting material in the vapor phase in the reaction vessel. The patent states:

The ion-exchanger column 1 is kept, by external heating and, if desired, by adding the reaction partners in vapor form, at a temperature sufficient to hold part of the reaction mixture, i.e., particularly the starting substance, in vapor form, without any significant recirculation existing in the reflux condenser 3.

Because the only other reference before the board, Alheritiere, discloses only esters and makes no mention of acetals or hemi-acetals, Enk must be relied upon to show that acetals and hemi-acetals are, in the context of the claimed invention, equivalent to esters. Without such a showing, Alheritiere is irrelevant to the claims at issue, which are confined solely to acetals and hemi-acetals.

[3] In answer to the solicitor's contention that the difference in the reactivity of esters and acetals is a new argument not properly before this court, we direct the solicitor's attention to appellant's reply brief, filed December 7, 1972, where he argues:

The Examiner takes the position [that Enk] equates the hydrolysis of esters and hydrolysis of acetals. However, the distinction between these materials which the Examiner overlooks is the fact that acetals are subject to deleterious side reactions such as ether formation and polymerization whereas esters are not.

This is a sufficient basis in the record presented to the board to merit our consideration of this issue in the present appeal.

[4] Our review of Enk's teachings convinces us that they fail to teach the equivalency between acetals and esters for the purposes of the present invention. A mere known relationship between acetals and esters as disclosed by the isolated portion of Enk upon which the board relied is insufficient to support the rejection. As distinguished from a disclosure of equivalents, the disclosure of a known relationship does nothing more than teach that it would have been obvious to try, which is insufficient under section 103. In re Lindell, 55 CCPA 707, 385 F.2d 453, 155 USPQ 521 (1967). Many compounds have a known relationship but are not equivalents for substitution in different reactions. A mere relationship is an insufficient basis for the necessary predictability of success to sustain a rejection un-

der section 103. See In re Naylor, 54 CCPA 902, 369 F.2d 765, 152 USPQ 106 (1966).

Appellant argues that significant aspects of the claimed invention are dissimilar to Alheritiere's reaction because there are no side reactions possible for the ester, whereas side reactions are often a problem in acetal and hemi-acetal hydrolysis and are disclosed in appellant's specification. Hydrolysis of esters results in the formation of a carboxylic acid and an alcohol. The acetal hydrolysis reaction, as noted above, results in the formation of an aldehyde and an alcohol. Consistent with appellant's position, we note that aldehydes are generally recognized to be inherently reactive compounds in the presence of the acidic catalysts required for the hydrolysis and form polymerization products because the carbonyl bond in the aldehyde is subject to attack by hydrogen ions present in the solution. Carboxylic acids are, by contrast, generally stable in acidic solutions and will not normally engage in side reactions of the type noted for the aldehydes. Accordingly, Enk's statement cannot be given the broad sweep required to sustain the rejection and may in fact be disbelieved for the purposes of specific liquid phase acid catalyzed hydrolysis reactions.

Considering the alleged teaching of equivalency in the context of all the relevant teachings of the references, we conclude that it must fail insofar as the process of Alheritiere is concerned, because the reference that is relied upon for the teaching is presented in the context of a prior art process that is significantly dissimilar to that of the claimed invention.

Given that Enk's "inventive contribution" cannot be ignored, the board has in substance agreed with this conclusion by finding that it was improper for the examiner to combine the two references "with respect to the inventive contribution of Enk et al."

[5] The conclusion that appellant's invention would have been nonobvious to one having ordinary skill in the art on the basis of the cited art is further buttressed by the fact that the claimed invention is a catalytic process. The unpredictability of catalytic phenomena has long been recognized by this court. As previously noted, Enk's disclosure is relied upon by the board for the proposition that organic oxygen-containing compounds, including acetals, may be hydrolyzed using the catalyst of appellant's invention. This does not render the process of appellant's invention any less unpredictable, because a successfully catalyzed process depends not only on the particular catalyst that may be employed but also on

the environment within which the catalysis is accomplished.

[6] The fact that the processing details of the claimed invention are substantially identical to those set forth in *Alheritiere* lends nothing to the rejection unless it can be shown that it would have been obvious to substitute acetals or hemi-acetals as reactants for the esters of *Alheritiere*. The adequacy of any such showing of equivalency must be scrutinized especially carefully, as we have attempted to do, where it is alleged to have been obvious to substitute one starting material for another in a catalytic process. The disclosure of *Enk*, relied upon by the board, is simply not sufficient for this purpose, especially in view of the over-all dissimilarity of the process of *Enk* to that of *Alheritiere*.

Other Rejections

We will follow the board's format and consider simultaneously the indefiniteness rejection based on the second paragraph of section 112, the alleged lack of antecedent basis for the claims in the specification required by Rule 75(d), 37 CFR 1.75(d), and the new matter rejection based on section 132, as well as an additional basis for the rejection found by the board based on the first paragraph of section 112. All of these rejections relate to appellant's use of the phrase "a fluidized catalyst" in claim 16, and each requires consideration of the same relevant portions of the specification.

The relevant portion of the second paragraph of section 112 has been construed to require only that the claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity." *In re Moore*, 58 CCPA 1042, 1046, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (1971); *In re Miller*, 58 CCPA 1182, 1186, 441 F.2d 689, 692, 169 USPQ 597, 599 (1971). As this court has reiterated on several occasions, "[i]n the absence of evidence to the contrary, we will assume * * * that what the claims define is what the applicant regards as his invention." (Emphasis added.) *In re Miller*, supra; *In re Moore*, supra.

[8] Applying this analysis, if one can determine whether a particular catalytic process for splitting acetals and hemi-acetals is or is not within the scope of a claim, the claim fulfills its purpose as a definition. See *In re Miller*, supra. Referring to the term in claim 16 which has been objected to, namely "fluidized," we note that appellant does not simply provide that the reaction mixture is passed "upwardly through a fluidized catalyst," but he goes on

to limit in some detail the physical and chemical characteristics of the catalyst and reaction mixture by concluding "said catalyst being a sulfonic ion exchange resin in acid form, at a temperature of 60° to 140° C. and a pressure sufficient to maintain the reaction mixture in the liquid phase." (Emphasis added.)

[9] Assuming, *arguendo* that the phrase "fluidized catalyst" is more often than not used to refer to a gas-suspended catalyst system, it does not follow that confusion will result when the phrase is used in a claim to refer to a finely divided catalyst in a dispersed or suspended state in a liquid phase. Whether a term used in a claim is conventional is not necessarily controlling on the question of indefiniteness. See *In re Castaing*, 57 CCPA 1332, 429 F.2d 461, 166 USPQ 550 (1970).

Since we are unable to see why or how there would be uncertainty over the plain meaning of the claim read in its entirety in view of the quoted portion which provides that the reaction mixture is in a liquid phase, the section 112 second paragraph rejection must be reversed.

Referring to the requirements of the first paragraph of section 112, the board found that the phrase "fluidized catalyst" "encompasses gas suspension of the catalyst which would not appear to be operative in the claimed process" and so "fails to find enabling support in the disclosure." The board also found that, since the criticized phrase first appeared in nonoriginal claim 15, it represents new matter introduced into the disclosure of the invention which is prohibited by the last sentence in 35 USC 132, and there is no original antecedent basis therefor in the specification as required by Rule 75(d).

We have already determined that the relevant portions of appellant's claims call for a "homogeneous liquid reaction mixture" which is passed "upwardly through a fluidized catalyst." Because the claims require the catalyst to be suspended by an upwardly flowing liquid reaction mixture, gas suspensions of the catalyst are clearly not within the scope of the claims.

We, therefore, find that appellant has fully complied with the first paragraph of section 112, and that the addition of the objected to phrase by amendment to the claims does not constitute a violation of the requirement of either the new matter prohibition of section 132 or the antecedent basis provision of Patent Office Rule 75(d).

Accordingly, the decision of the board is reversed.

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Markey, Chief Judge, dissenting.

Appellant's sole contribution to the art is the proposal to use Alheritiere's process, apparatus and catalyst in the hydrolysis of acetals instead of esters. But Enk says that those skilled in the art had long known that acetals could be hydrolyzed in the presence of the same catalyst. Appellant does not deny, and nowhere attempts to disprove the truth of Enk's statement. Lack of explicit suggestion of the substitution is not fatal to a finding of obviousness. *In re Lindell*, 55 CCPA 707, 385 F.2d 453, 155 USPQ 521 (1967). The probative question is what Enk's disclosure means to those skilled in the art. *In re Baranauckas*, 55 CCPA 1204, 395 F.2d 805, 158 USPQ 24 (1968).

That Enk does not supply temperatures, pressures and the like is of no moment. Alheritiere supplies them.

The unpredictability of catalytic processes loses import here. Enk, Alheritiere and appellant all employ the same catalyst.

The alcohol formed in the hydrolysis of both esters and acetals is capable of side reaction. As recognized in appellant's specification, temperatures must be limited to avoid risk of such alcohol reaction.

Enk's invention is totally irrelevant. It does not in any manner refute or conflict with the statement of Enk concerning the knowledge and level of skill in the art. Nor does it suggest that acetals could not be hydrolyzed in Alheritiere's process and apparatus.

Finding no error in the board's upholding of the examiner's rejection under 35 USC 103, I would affirm its decision.

Court of Customs and Patent Appeals

In re Buehler

No. 74-613 Decided May 22, 1975

PATENTS

1. Patentability — Evidence of — Suggestions of prior art (§51.469)

Patentability — Invention — In general (§51.501)

Claimed method that involves doing what prior art reference tries to avoid is very antithesis of obviousness.

2. Construction of specification and claims — Defining terms (§22.45)

Specification may be used as dictionary to learn meaning of terms in claim.

3. Double patenting — Tests of (§33.9)

Questions in double patenting are (1) whether identical subject matter or "same invention" is being claimed twice and (2) whether any claim in application defines merely obvious variation of invention claimed in patent.

Particular patents — Wire Casting

Buehler, Method and Apparatus for Continuously Casting Wire or the Like, rejection of claims 8-14 and 23-28 reversed.

Appeal from Board of Appeals of the Patent and Trademark Office.

Application for patent of William J. Buehler, Serial No. 788,135, filed Dec. 31, 1968; Patent and Trademark Office Group 322. From decision rejecting claims 8-14 and 23-28, applicant appeals. Reversed; Rich, J., and Markey, Ch. J., dissenting with opinion.

Paul M. Craig, Washington, D. C., for appellant.

Joseph F. Nakamura (Henry W. Tarr, II, of counsel) for Commissioner of Patents and Trademarks.

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

Lane, Judge.

This appeal is from the decision of the Patent and Trademark Office Board of Appeals affirming the rejection of all claims (8-14 and 23-28) in appellant's patent application serial No. 788,135, filed December 31, 1968, for "Method and Apparatus for Continuously Casting Wire or the Like." All claims were rejected on two grounds: (1) obvious subject matter under 35 USC 103, and (2) double patenting of the "obviousness-type" wherein no terminal disclaimer has been filed. We reverse.

The Invention

Appellant's invention pertains to a method of continuously casting 55-Nitinol,¹ which is a specific titanium-nickel (Ti-Ni) alloy, into relatively small wire or flat ribbon

¹ "Nitinol" is an acronym derived as follows: Ni is from nickel, Ti is from titanium, and NOL is from Naval Ordnance Laboratory at White Oak, Maryland, where this alloy was developed. "55" refers to 55% by weight of Ni in the alloy.

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